

CORTICOSTEROIDS Glucocorticoid Effects (Systemic)

Introduction

VA CLASSIFICATION (Primary/Secondary)

Betamethasone³⁴/HS051/IM403

Budesonide³⁴/HS051

Cortisone³⁴/HS051/

Dexamethasone³⁴/HS051/; GA609; IM403

Hydrocortisone³⁴/HS051/; IM403

Methylprednisolone³⁴/HS051/

Prednisolone³⁴/HS051/

Prednisone³⁴/HS051/; IM403

Triamcinolone³⁴/HS051/

Indications

Accepted

Allergic disorders³⁴Indicated for the treatment of severe or incapacitating allergic disorders intractable to adequate trials of conventional treatment

Allergic reactions, drug-induced (treatment)³⁴Betamethasone (sodium phosphate and acetate injectable suspension, 3 syrup, 1 tablets 27); cortisone (acetate injectable suspension, 4, 30 tablets 5, 31); dexamethasone (acetate injectable suspension, 9 elixir, 6 oral solution, 25 sodium phosphate injection, 8, 33 tablets 7, 25, 34); hydrocortisone (cypionate oral suspension, 44 sodium phosphate injection, 12 sodium succinate for injection, 13 tablets 11, 36, 37); methylprednisolone (acetate injectable suspension, 26 sodium succinate for injection, 18, 43, 45 tablets 28, 41); prednisolone (sodium phosphate oral solution, 19 syrup 21); prednisone (tablets 46, 47, 48); and triamcinolone (tablets 49).

Anaphylactic or anaphylactoid reactions (treatment adjunct)³⁴Dexamethasone (sodium phosphate injection 33); hydrocortisone (sodium succinate for injection 13); and methylprednisolone (sodium succinate for injection 45) are indicated as adjunctive treatment in prolonged reactions (those not responding to other forms of treatment within 1 hour), reactions requiring cardiovascular or respiratory resuscitation, or situations in which there is a significant risk of relapse.

Epinephrine is the drug of choice for this indication. 33, 45

Angioedema (treatment adjunct)³⁴Betamethasone (tablets 61) is indicated as an adjunct in the treatment of angioedema. Treatment should be initiated with intramuscular or intravenous administration of a rapid-acting preparation.

Edema, laryngeal, acute noninfectious (treatment adjunct)³⁴Betamethasone (sodium phosphate and acetate injectable suspension 3); cortisone (acetate injectable suspension, 4, 30 tablets 5); dexamethasone (sodium phosphate injection 8, 33); hydrocortisone (sodium phosphate injection, 12 sodium succinate for injection 13); and methylprednisolone (acetate injectable suspension, 26 sodium succinate for injection 18, 43) are indicated as adjuncts in the treatment of acute noninfectious laryngeal edema. Treatment should be initiated with intramuscular or intravenous administration of a rapid-acting preparation.

Epinephrine is the drug of choice for this indication. 3, 4, 5, 8, 12, 13, 18, 26, 30, 43

Rhinitis, allergic, perennial or seasonal, severe (treatment) ¼Betamethasone (sodium phosphate and acetate injectable suspension, 3 syrup, 1 tablets 27, 58, 61); cortisone (acetate injectable suspension, 4, 30 tablets 5, 31); dexamethasone (acetate injectable suspension, 9 elixir, 6 oral solution, 25 sodium phosphate injection, 8, 33 tablets 7, 25); hydrocortisone (cypionate oral suspension, 44 sodium phosphate injection, 12 sodium succinate for injection, 13 tablets 11, 36, 37); methylprednisolone (acetate injectable suspension, 26 sodium succinate for injection, 18, 43 tablets 28, 41); prednisolone (sodium phosphate oral solution, 19 syrup 21); prednisone (tablets 46, 47, 48); and triamcinolone (acetone injectable suspension, 51 tablets 49).

Serum sickness (treatment)¼Betamethasone (sodium phosphate and acetate injectable suspension, 3 syrup, 1 tablets 27, 61); cortisone (acetate injectable suspension, 4, 30 tablets 5, 31); dexamethasone (acetate injectable suspension, 9 elixir, 6 oral solution, 25 sodium phosphate injection, 8, 33 tablets 7, 25, 34); hydrocortisone (cypionate oral suspension, 44 sodium phosphate injection, 12 sodium succinate for injection, 13 tablets 11, 36, 37); methylprednisolone (acetate injectable suspension, 26 sodium succinate for injection, 18, 43, 45 tablets 28, 41); prednisolone (sodium phosphate oral solution, 19 syrup 21); prednisone (tablets 47, 48); and triamcinolone (tablets 49).

Transfusion reactions, urticarial (treatment)¼ Betamethasone (sodium phosphate and acetate injectable suspension 3); cortisone (acetate injectable suspension, 4, 30 tablets 5); dexamethasone (acetate injectable suspension, 9 sodium phosphate injection 8, 33); hydrocortisone (sodium phosphate injection, 12 sodium succinate for injection 13); and methylprednisolone (acetate injectable suspension, 26 sodium succinate for injection 18, 43) are indicated in the treatment of urticarial transfusion reactions. Treatment should be initiated with intramuscular or intravenous administration of a rapid-acting preparation.

Collagen disorders¼Indicated during an acute exacerbation or as maintenance therapy

Arteritis, giant cell (treatment)¼Methylprednisolone (tablets 41); and prednisone (tablets 47).

Carditis, rheumatic [or nonrheumatic] *, acute (treatment)¼Betamethasone (sodium phosphate and acetate injectable suspension, 3 syrup, 1 tablets 27, 61); cortisone (acetate injectable suspension, 4, 30 tablets 5, 31); dexamethasone (acetate injectable suspension, 9 elixir, 6 oral solution, 25 sodium phosphate injection, 8, 33 tablets 7, 25, 34); hydrocortisone (cypionate oral suspension, 44 sodium phosphate injection, 12 sodium succinate for injection, 13 tablets 11, 36, 37); methylprednisolone (acetate injectable suspension, 26 sodium succinate for injection, 18, 43 tablets 28, 41); prednisolone (sodium phosphate oral solution, 19 syrup 21); prednisone (oral solution, tablets 46, 47, 48); and triamcinolone (tablets 49).

Dermatomyositis, systemic (polymyositis) (treatment)¼Cortisone (acetate injectable suspension, 4, 30 tablets 5, 31); hydrocortisone (cypionate oral suspension, 44 sodium phosphate injection, 12 sodium succinate for injection, 13 tablets 36, 37); methylprednisolone (acetate injectable suspension, 26 sodium succinate for injection, 18, 43 tablets 28, 41); prednisolone (sodium phosphate oral solution, 19 syrup 21); and prednisone (tablets 46, 47, 48).

Lupus erythematosus, systemic (treatment)¼Betamethasone (sodium phosphate and acetate injectable suspension, 3 syrup, 1 tablets 27, 61); cortisone (acetate injectable suspension, 4, 30 tablets 5, 31);

dexamethasone (acetate injectable suspension, 9 elixir, 6 oral solution, 25 sodium phosphate injection, 8, 33 tablets 7, 25, 34); hydrocortisone (cypionate oral suspension, 44 sodium phosphate injection, 12 sodium succinate for injection, 13 tablets 11, 36, 37); methylprednisolone (acetate injectable suspension, 26 sodium succinate for injection, 18, 43, 45 tablets 28, 41); prednisolone (sodium phosphate oral solution, 19 syrup 21); prednisone (tablets 46, 47, 48); and triamcinolone (tablets 49).

[Connective tissue disease, mixed (treatment)] *

[Polyarteritis nodosa (treatment)] *

[Polychondritis, relapsing (treatment)] * and

[Vasculitis (treatment)] *¼Betamethasone; cortisone; dexamethasone; hydrocortisone; methylprednisolone; prednisolone; prednisone; and triamcinolone.

[Depression, mental, endogenous (diagnosis)] *¼Dexamethasone is indicated to diagnose endogenous depression and to evaluate the efficacy of treatment. Dexamethasone reduces plasma cortisol to a greater extent in control subjects than in hospitalized patients with diagnosed depression; values return toward those of control subjects as the patient responds to therapy. However, the dexamethasone suppression test is less sensitive in patients with mild to moderate depression. Also, many medications, medical problems, and other psychiatric disorders have been reported to interfere with the test results. The Health and Public Policy Committee of the American College of Physicians recommends that the dexamethasone suppression test not be used as a screening test for depression.

Dermatologic disorders

Alopecia areata (treatment)¼Betamethasone (sodium phosphate and acetate injectable suspension 3); dexamethasone (acetate injectable suspension, 9 sodium phosphate injection 8, 33); hydrocortisone (acetate injectable suspension 10); methylprednisolone (acetate injectable suspension 26); and triamcinolone (acetamide injectable suspension 50).

Dermatitis, atopic (treatment)¼Betamethasone (sodium phosphate and acetate injectable suspension, 3 syrup, 1 tablets 27, 61); cortisone (acetate injectable suspension, 4, 30 tablets 5, 31); dexamethasone (acetate injectable suspension, 9 elixir, 6 oral solution, 25 sodium phosphate injection, 8, 33 tablets 7, 25, 34); hydrocortisone (cypionate oral suspension, 44 sodium phosphate injection, 12 sodium succinate for injection, 13 tablets 11, 36, 37); methylprednisolone (acetate injectable suspension, 26 sodium succinate for injection, 18, 43 tablets 28, 41); prednisolone (sodium phosphate oral solution, 19 syrup 21); prednisone (tablets 46, 47, 48); and triamcinolone (tablets 49).

Dermatitis, contact (treatment)¼Betamethasone (sodium phosphate and acetate injectable suspension, 3 syrup, 1 tablets 27, 61); cortisone (acetate injectable suspension, 4, 30 tablets 5, 31); dexamethasone (acetate injectable suspension, 9 elixir, 6 oral solution, 25 sodium phosphate injection, 8, 33 tablets 7, 25, 34); hydrocortisone (cypionate oral suspension, 44 sodium phosphate injection, 12 sodium succinate for injection, 13 tablets 11, 36, 37); methylprednisolone (acetate injectable suspension, 26 sodium succinate for injection, 18, 43, 45 tablets 28, 41); prednisolone (sodium phosphate oral solution, 19 syrup 21); prednisone (tablets 46, 47, 48); and triamcinolone (tablets 49).

Dermatitis, exfoliative (treatment)¼Betamethasone (sodium phosphate and acetate injectable suspension, 3 syrup, 1 tablets 27, 61); cortisone (acetate injectable suspension, 4, 30 tablets 5, 31); dexamethasone (acetate injectable suspension, 9 elixir, 6 oral solution, 25 sodium phosphate injection, 8, 33 tablets 7, 25, 34); hydrocortisone (cypionate oral suspension, 44 sodium phosphate injection, 12 sodium succinate for injection, 13 tablets 11, 36, 37); methylprednisolone (acetate injectable suspension, 26 sodium succinate for injection, 18, 43, 45 tablets 28, 41); prednisolone (sodium phosphate oral solution, 19 syrup 21); prednisone (tablets 46, 47, 48); and triamcinolone (tablets 49).

Dermatitis herpetiformis, bullous (treatment)¼ Betamethasone (sodium phosphate and acetate injectable suspension, 3 syrup, 1 tablets 27, 61); cortisone (acetate injectable suspension, 30 tablets 31); dexamethasone (acetate injectable suspension, 9 elixir, 6 oral solution, 25 sodium phosphate injection, 8, 33 tablets 7, 25, 34); hydrocortisone (cypionate oral suspension, 44 sodium phosphate injection, 12 sodium succinate for injection, 13 tablets 11, 36, 37); methylprednisolone (acetate injectable suspension, 26 sodium succinate for injection, 18, 43 tablets 28, 41); prednisolone (sodium phosphate oral solution, 19 syrup 21); prednisone (tablets 46, 47, 48); and triamcinolone (tablets 49).

Dermatitis, seborrheic, severe (treatment)¼Betamethasone (sodium phosphate and acetate injectable suspension, 3 syrup, 1 tablets 27); cortisone (acetate injectable suspension, 4, 30 tablets 5, 31); dexamethasone (acetate injectable suspension, 9 elixir, 6 oral solution, 25 sodium phosphate injection, 8, 33 tablets 7, 25, 34); hydrocortisone (cypionate oral suspension, 44 sodium phosphate injection, 12 sodium succinate for injection, 13 tablets 11, 36, 37); methylprednisolone (acetate injectable suspension, 26 sodium succinate for injection, 18, 43 tablets 28, 41); prednisolone (sodium phosphate oral solution, 19 syrup 21); prednisone (tablets 46, 47, 48); and triamcinolone (tablets 49).

Dermatoses, inflammatory, severe (treatment)¼Betamethasone (tablets 58) and triamcinolone (acetamide injectable suspension, 51 tablets 49).

Erythema multiforme, severe (Stevens-Johnson syndrome) (treatment) ¼Betamethasone (sodium phosphate and acetate injectable suspension, 3 syrup, 1 tablets 27, 61); cortisone (acetate injectable suspension, 4, 30 tablets 5, 31); dexamethasone (acetate injectable suspension, 9 elixir, 6 oral solution, 25 sodium phosphate injection, 8, 33 tablets 7, 25, 34); hydrocortisone (cypionate oral suspension, 44 sodium phosphate injection, 12 sodium succinate for injection, 13 tablets 11, 36, 37); methylprednisolone (acetate injectable suspension, 26 sodium succinate for injection, 18, 43, 45 tablets 28, 41); prednisolone (sodium phosphate oral solution, 19 syrup 21); prednisone (tablets 46, 47, 48); and triamcinolone (tablets 49).

Granuloma annulare (treatment)¼Betamethasone (sodium phosphate and acetate injectable suspension 3); dexamethasone (acetate injectable suspension, 9 sodium phosphate injection 8, 33); hydrocortisone (acetate injectable suspension 10) methylprednisolone (acetate injectable suspension 26); and triamcinolone (acetamide injectable suspension 50).

Keloids (treatment)¼Betamethasone (sodium phosphate and acetate injectable suspension 3); dexamethasone (acetate injectable suspension, 9 sodium phosphate injection 8, 33); hydrocortisone (acetate injectable suspension 10); methylprednisolone (acetate injectable suspension 26); and triamcinolone (acetamide injectable suspension 50).

Lichen planus (treatment)¼Betamethasone (sodium phosphate and acetate injectable suspension 3); dexamethasone (acetate injectable suspension, 9 sodium phosphate injection 8, 33); hydrocortisone (acetate injectable suspension 10); methylprednisolone (acetate injectable suspension 26); and triamcinolone (acetate injectable suspension 50).

Lichen simplex chronicus (neurodermatitis) (treatment)¼Betamethasone (sodium phosphate and acetate injectable suspension 3); dexamethasone (acetate injectable suspension, 9 sodium phosphate injection 8, 33); hydrocortisone (acetate injectable suspension 10); methylprednisolone (acetate injectable suspension 26); and triamcinolone (acetate injectable suspension 50).

Lupus erythematosus, discoid (treatment)¼Betamethasone (sodium phosphate and acetate injectable suspension 3); dexamethasone (acetate injectable suspension, 9 sodium phosphate injection 8, 33); hydrocortisone (acetate injectable suspension 10); methylprednisolone (acetate injectable suspension 26); and triamcinolone (acetate injectable suspension 50).

Mycosis fungoides (treatment)¼Betamethasone (sodium phosphate and acetate injectable suspension, 3 syrup, 1 tablets 27, 61); cortisone (acetate injectable suspension, 4, 30 tablets 5, 31); dexamethasone (acetate injectable suspension, 9 elixir, 6 oral solution, 25 sodium phosphate injection, 8, 33 tablets 7, 25, 34); hydrocortisone (cypionate oral suspension, 44 sodium phosphate injection, 12 sodium succinate for injection, 13 tablets 11, 36, 37); methylprednisolone (acetate injectable suspension, 26 sodium succinate for injection, 18, 43 tablets 28, 41); prednisolone (sodium phosphate oral solution, 19 syrup 21); prednisone (tablets 46, 47, 48); and triamcinolone (tablets 49).

Necrobiosis lipoidica diabetorum (treatment)¼ Betamethasone (sodium phosphate and acetate injectable suspension 3); dexamethasone (acetate injectable suspension, 9 sodium phosphate injection 8, 33); hydrocortisone (acetate injectable suspension 10); methylprednisolone (acetate injectable suspension 26); and triamcinolone (acetate injectable suspension 50).

Pemphigus (treatment)¼Betamethasone (sodium phosphate and acetate injectable suspension, 3 syrup, 1 tablets 27, 61); cortisone (acetate injectable suspension, 4, 30 tablets 5, 31); dexamethasone (acetate injectable suspension, 9 elixir, 6 oral solution, 25 sodium phosphate injection, 8, 33 tablets 7, 25, 34); hydrocortisone (cypionate oral suspension, 44 sodium phosphate injection, 12 sodium succinate for injection, 13 tablets 11, 36, 37); methylprednisolone (acetate injectable suspension, 26 sodium succinate for injection, 18, 43, 45 tablets 28, 41); prednisolone (sodium phosphate oral solution, 19 syrup 21); prednisone (tablets 46, 47, 48); and triamcinolone (tablets 49).

Psoriasis, severe (treatment)¼Betamethasone (sodium phosphate and acetate injectable suspension, 3 syrup, 1 tablets 27, 61); cortisone (acetate injectable suspension, 4, 30 tablets 5, 31); dexamethasone (acetate injectable suspension, 9 elixir, 6 oral solution, 25 sodium phosphate injection, 8, 33 tablets 7, 25, 34); hydrocortisone (cypionate oral suspension, 44 sodium phosphate injection, 12 sodium succinate for injection, 13 tablets 11, 36, 37); methylprednisolone (acetate injectable suspension, 26 sodium succinate for injection, 18, 43 tablets 28, 41); prednisolone (sodium phosphate oral solution, 19 syrup 21); prednisone (tablets 46, 47, 48); and triamcinolone (tablets 49).

Psoriatic plaques (treatment)¼Betamethasone (sodium phosphate and acetate injectable suspension 3); dexamethasone (acetate injectable suspension, 9 sodium phosphate injection 8, 33); hydrocortisone

(acetate injectable suspension 10); methylprednisolone (acetate injectable suspension 26); and triamcinolone (acetate injectable suspension 50).

[Eczema, severe (treatment)]⁴ Betamethasone (tablets 58); cortisone *; dexamethasone *; hydrocortisone *; methylprednisolone *; prednisolone *; prednisone *; and triamcinolone *.

[Pemphigoid (treatment)]³ Betamethasone; cortisone; dexamethasone; hydrocortisone; methylprednisolone; prednisolone; prednisone; and triamcinolone.

[Sarcoid, localized cutaneous (treatment)]³ Betamethasone; dexamethasone; hydrocortisone; methylprednisolone; prednisolone; and triamcinolone.

Precautions to Consider

Pregnancy/Reproduction

Fertility⁴ Corticosteroids have been reported to increase or decrease the number or motility of spermatozoa. 4, 6, 10, 20, 30, 33, 58 However, it is not known whether reproductive capacity in humans is adversely affected.

Pregnancy⁴ For corticosteroids⁴

Corticosteroids cross the placenta. 29, 36, 42, 47 Although adequate studies have not been done in humans, there is some evidence that pharmacologic doses of corticosteroids may increase the risk of placental insufficiency, decreased birthweight, or stillbirth. However, teratogenic effects in humans have not been confirmed.

Prenatal administration of betamethasone or dexamethasone to the pregnant woman to prevent respiratory distress syndrome in the premature neonate has not been shown to affect the child's growth or development adversely. Physiologic replacement doses of corticosteroids administered for treatment of maternal adrenal insufficiency also are unlikely to adversely affect the fetus or neonate.

Studies in animals have shown that corticosteroids increase the incidence of cleft palate, 20, 50 placental insufficiency, spontaneous abortions, and intrauterine growth retardation.

FDA Pregnancy Category C (Prednisolone). 19

For budesonide⁴

High doses of budesonide administered subcutaneously produced fetal malformations (primarily skeletal defects) in rabbits, rats, and mice. However, the relevance of these findings to humans has not been established. 29

Breast-feeding

For corticosteroids⁴ Problems in humans have not been documented. Administration of physiologic doses or low pharmacologic doses (the equivalent or less of 25 mg of cortisone or 5 mg of prednisone per day) is not considered likely to affect the infant adversely. Less than 1% of the administered dose of prednisolone is distributed into breast milk. 19 However, breast-feeding during the use of higher pharmacologic doses is not recommended because corticosteroids are distributed into breast milk 4, 6, 10, 20, 29, 30, 33, 36, 42, 47, 50 and may cause unwanted effects, such as growth suppression and inhibition of endogenous steroid production, in the infant. 4, 6, 10, 30, 33, 50

Pediatrics

Infants born to women who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism 3, 4, 6, 10, 18, 20, 21, 29, 30, 33, 36, 42, 46, 47, 50, 58 and replacement therapy should be administered as required. 3

Because infections such as chickenpox or measles may be more serious (or even fatal) in children receiving immunosuppressant doses of corticosteroids, extra care to avoid exposure to these infections is recommended. 3, 4, 10, 18, 20, 21, 33, 36, 46, 50 Prophylactic therapy with varicella zoster immune globulin (VZIG) or immune globulin intravenous (IGIV) or intramuscular (IGIM), as appropriate, may be indicated in exposed patients. 3, 4, 6, 10, 18, 20, 21, 29, 33, 36, 46, 50, 58 Therapy with an antiviral agent may be indicated if chickenpox develops. 3, 4, 6, 10, 18, 20, 21, 29, 33, 36, 46, 50

Chronic use of corticosteroids may suppress growth and development of the pediatric or adolescent patient and should be undertaken with caution. 42, 47 Use of long-acting glucocorticoids (betamethasone and dexamethasone) or daily doses of any corticosteroid that are larger than replacement therapy doses are especially likely to inhibit growth and are not recommended for any form of chronic therapy. For long-term therapy, a short-acting agent (cortisone or hydrocortisone) or an intermediate-acting agent (methylprednisolone, prednisolone, prednisone, or triamcinolone) is recommended. Alternate-day therapy with an oral intermediate-acting corticosteroid may decrease growth retardation effects. 42, 47 Some clinicians recommend that only cortisone, hydrocortisone, or prednisone be used for long-term replacement therapy. Also, pediatric patients may be at increased risk of developing osteoporosis, avascular necrosis of the femoral heads, glaucoma, or cataracts during prolonged therapy. Children and adolescents receiving prolonged therapy should be closely monitored. Pediatric dosage is determined more by the severity of the condition and the response of the patient than by age or body weight. 47 Also, for treatment of adrenocortical insufficiency, pediatric dosage is preferably determined in terms of mg per square meter of body surface area. Determination of pediatric dosage in terms of mg per kg of body weight (mg/kg) increases the possibility of overdosage, especially in very young, short, or heavy children.

Geriatrics

Geriatric patients may be more likely to develop hypertension during corticosteroid therapy. 50 Geriatric patients, especially postmenopausal women, also may be more likely to develop glucocorticoid-induced osteoporosis.

Drug interactions and/or related problems

The following drug interactions and/or related problems have been selected on the basis of their potential clinical significance (possible mechanism in parentheses where appropriate) not necessarily inclusive (>> = major clinical significance):

See also Laboratory value alterations.

Note: Combinations containing any of the following medications, depending on the amount present, also may interact with this medication.

Interactions listed below involving alterations in serum potassium concentration and/or changes in sodium or fluid balance are especially likely to occur with corticosteroids having significant

mineralocorticoid activity. However, these interactions also may occur with other corticosteroids, depending on dosage and patient predisposition.

Acetaminophen

(induction of hepatic enzymes by corticosteroids may increase the formation of a hepatotoxic acetaminophen metabolite, thereby increasing the risk of hepatotoxicity, when they are used concurrently with chronic or high-dose acetaminophen therapy)

Alcohol or

Anti-inflammatory drugs, nonsteroidal (NSAIDs)

(risk of gastrointestinal ulceration or hemorrhage may be increased when these substances are used concurrently with glucocorticoids; however, concurrent use of NSAIDs in the treatment of arthritis may provide additive therapeutic benefit and permit glucocorticoid dosage reduction)

>> Aminoglutethimide

(aminoglutethimide suppresses adrenal function so that glucocorticoid supplementation may be required; however, aminoglutethimide accelerates the metabolism of dexamethasone so that the half-life of dexamethasone may be reduced twofold; hydrocortisone is recommended instead because its metabolism is not known to be altered by aminoglutethimide and because its mineralocorticoid activity also may be required)

>> Amphotericin B, parenteral 33, 50 or

Carbonic anhydrase inhibitors

(concurrent use with corticosteroids may result in severe hypokalemia and should be undertaken with caution; 50 serum potassium concentrations and cardiac function should be monitored during concurrent use)

(the use of hydrocortisone to control adverse reactions to amphotericin B has resulted in cases of cardiac enlargement and congestive heart failure 12, 33)

(concurrent use of corticosteroids with acetazolamide sodium may increase the risk of hyponatremia and/or edema because corticosteroids cause sodium and fluid retention; the risk with corticosteroids may depend on the patient's sodium requirement as determined by the condition being treated)

(the possibility should be considered that concurrent chronic use of both carbonic anhydrase inhibitors and corticosteroids may increase the risk of hypocalcemia and osteoporosis because carbonic anhydrase inhibitors also increase calcium excretion)

Anabolic steroids or

Androgens

(concurrent use with glucocorticoids may increase the risk of edema; also, concurrent use may promote the development of severe acne)

>> Antacids

(concurrent chronic use with prednisone or dexamethasone may decrease absorption of these glucocorticoids; efficacy may be decreased sufficiently to require dosage adjustment in patients receiving small doses, but probably not in those receiving large doses, of the corticosteroid)

Anticholinergics, especially atropine and related compounds

(concurrent long-term use with glucocorticoids may increase intraocular pressure)

Anticoagulants, coumarin- or indanedione-derivative 4, 6, 10, 18, 20, 30, 33, 36, 42, 47, 50 or

Heparin or

Streptokinase or

Urokinase

(effects of coumarin or indanedione derivatives usually are decreased [but may be increased in some patients] when these medications are used concurrently with glucocorticoids; 4, 6, 10, 18, 30, 33, 36, 42, 47, 50 dosage adjustments based on prothrombin time determinations may be necessary during and after glucocorticoid therapy)

(the potential occurrence of gastrointestinal ulceration or hemorrhage during glucocorticoid therapy, and the effects of glucocorticoids on vascular integrity, may cause increased risk to patients receiving anticoagulant or thrombolytic therapy)

Antidepressants, 50 tricyclic

(these medications do not relieve, and may exacerbate, corticosteroid-induced mental disturbances; they should not be used for treatment of these adverse effects 50)

>> Antidiabetic agents, oral 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58 or

>> Insulin 3, 4, 6, 10, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58

(glucocorticoids may increase blood glucose concentration; 30, 50 dosage adjustment of one or both agents may be necessary during concurrent use; 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 58 dosage readjustment of the hypoglycemic agent also may be required when glucocorticoid therapy is discontinued)

Antithyroid agents or

Thyroid hormones 50

(changes in the thyroid status of the patient that may occur as a result of administration, changes in dosage, or discontinuation of thyroid hormones or antithyroid agents may necessitate adjustment of corticosteroid dosage because metabolic clearance of corticosteroids is decreased in hypothyroid patients and increased in hyperthyroid patients; 50 dosage adjustment should be based on results of thyroid function tests 50)

Asparaginase

(glucocorticoids, especially prednisone, may increase the hyperglycemic effect of asparaginase and the risk of neuropathy and disturbances in erythropoiesis; the toxicity appears to be less pronounced when asparaginase is administered following, rather than before or with, these medications)

Contraceptives, oral, estrogen-containing 50 or

Estrogens 20, 50

(estrogens may alter the metabolism and protein binding of glucocorticoids, leading to decreased clearance, increased elimination half-life, and increased therapeutic and toxic effects of the glucocorticoid; glucocorticoid dosage adjustment may be required during and following concurrent use 20)

>> Cyclosporine 18, 20, 42, 47, 50

(seizures have been observed in patients receiving cyclosporine and high doses of methylprednisolone 18, 42, 47)

>> Digitalis glycosides 20, 50

(concurrent use with glucocorticoids may increase the possibility of arrhythmias or digitalis toxicity 20, 50 associated with hypokalemia)

>> Diuretics 4, 6, 10, 20, 30, 33

(natriuretic and diuretic effects of these medications may be decreased by sodium- and fluid-retaining actions of corticosteroids, and vice versa)

(concurrent use of potassium-depleting diuretics with corticosteroids may result in severe hypokalemia; 4, 6, 10, 20, 30, 33 monitoring of serum potassium concentration and cardiac function is recommended)

(effects of potassium-sparing diuretics and/or corticosteroids on serum potassium concentration may be decreased during concurrent use; monitoring of serum potassium concentration is recommended)

Ephedrine 4, 6, 10, 20, 30, 33 or

Phenobarbital 4, 6, 10, 18, 20, 30, 33, 36, 42, 47, 50 or

Phenytoin 4, 6, 10, 18, 20, 30, 33, 36, 42, 47, 50, 58 or

Rifampin 4, 6, 10, 18, 20, 30, 33, 36, 42, 47, 50

(concurrent use may increase the metabolic clearance of corticosteroids; 50 corticosteroid dosage adjustment may be required during and following concurrent use 4, 6, 10, 18, 20, 30, 33, 36, 42, 47, 50, 58)

Folic acid

(requirements may be increased in patients receiving long-term corticosteroid therapy)

>> Hepatic enzyme-inducing agents (see Appendix II)

(concurrent use may decrease the corticosteroid effect because of increased corticosteroid metabolism resulting from induction of hepatic microsomal enzymes)

Immunosuppressant agents, other

(concurrent use with immunosuppressant doses of glucocorticoids may increase the risk of infection and possibly the development of lymphomas or other lymphoproliferative disorders; these neoplasms may be associated with Epstein-Barr virus infections; a few studies in organ transplant patients receiving immunosuppressant therapy indicate that progression of the neoplasm may be reversed after immunosuppressant dosage is decreased or therapy is discontinued)

Iophendylate or

Metrizamide

(concurrent intrathecal administration of metrizamide or iophendylate with intrathecal administration of glucocorticoids may increase the risk of arachnoiditis)

Isoniazid 20, 50

(glucocorticoids, especially prednisolone, may increase hepatic metabolism and/or excretion of isoniazid, leading to decreased plasma concentration and effectiveness of isoniazid, 20, 50 especially in patients who are rapid acetylators; isoniazid dosage adjustment may be required during and following concurrent use)

Mexiletine

(concurrent use with glucocorticoids may accelerate metabolism of mexiletine, leading to decreased mexiletine plasma concentration)

>> Mitotane

(mitotane suppresses adrenocortical function; glucocorticoid supplementation usually is required during mitotane administration, but higher doses than those generally used for replacement therapy may be required because mitotane alters glucocorticoid metabolism)

Neuromuscular blocking agents, nondepolarizing

(hypokalemia induced by glucocorticoids may enhance the blockade of nondepolarizing neuromuscular blocking agents, possibly leading to increased or prolonged respiratory depression or paralysis [apnea]; serum potassium determinations may be necessary prior to administration of these agents)

(hydrocortisone and prednisone also have been reported to decrease the efficacy of pancuronium by an unknown mechanism; increased dosage of pancuronium or use of an alternate neuromuscular blocking agent may be necessary)

>> Potassium supplements

(effects of these medications and/or corticosteroids on serum potassium concentration may be decreased when these medications are used concurrently; monitoring of serum potassium concentration is recommended)

>> Ritodrine

(concurrent use may cause pulmonary edema in the pregnant woman; maternal death has been reported; both medications should be discontinued at the first sign of pulmonary edema)

Salicylates 3, 4, 6, 10, 18, 20, 21, 29, 33, 36, 42, 46, 47, 50, 58

(although concurrent use with glucocorticoids in the treatment of arthritis may provide additive therapeutic benefit and permit glucocorticoid dosage reduction, glucocorticoids may increase salicylate excretion and reduce salicylate plasma concentrations so that the salicylate dosage requirement may be increased; 18, 36, 42, 47, 50 salicylism may occur when glucocorticoid dosage is subsequently decreased or discontinued, especially in patients receiving large [antirheumatic] doses of salicylates; 18, 36, 42, 47, 50 also, the risk of gastrointestinal ulceration or hemorrhage may be increased during concurrent use)

(caution is recommended when salicylates are used concurrently with corticosteroids in patients with hypoprothrombinemia 6, 10, 18, 20, 21, 33, 36, 42, 46, 47, 50)

>> Sodium-containing medications or foods

(concurrent use with pharmacologic doses of glucocorticoids may result in edema and increased blood pressure, possibly to hypertensive levels)

(although patients receiving replacement doses of glucocorticoids may require sodium supplementation, adjustment of dietary sodium intake may be required when a medication having a high sodium content is administered concurrently)

>> Somatrem 50 or

>> Somatropin

(inhibition of the growth response to somatrem 50 or somatropin may occur with chronic therapeutic use of daily doses [per square meter of body surface area] in excess of:

	Oral	Parenteral
Betamethasone	300-450 mcg	150-225 mcg
Cortisone	12.5-18.8 mg	6.25-9.4 mg
Dexamethasone	375-563 mcg	187.5-281.5 mcg

Hydrocortisone	10-15 mg	5-7.5 mg
Methylprednisolone	2-3 mg	1-1.5 mg
Prednisolone	2.5-3.75 mg	1.25-1.88 mg
Prednisone	2.5-3.75 mg	
Triamcinolone	2-3 mg	1-1.5 mg

It is recommended that these doses not be exceeded during somatrem or somatropin therapy; if larger doses are required, administration of somatrem or somatropin should be postponed)

Streptozocin

(concurrent use with glucocorticoids may increase the risk of hyperglycemia)

Troleandomycin 18, 36, 42, 47

(troleandomycin may decrease metabolism of methylprednisolone and possibly other glucocorticoids, leading to increased plasma concentration, elimination half-life, and therapeutic and toxic effects; 18, 36, 42, 47 glucocorticoid dosage adjustment may be required during and following concurrent use 18, 36, 42, 47)

>> Vaccines, live virus, or other immunizations 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58

(administration of live virus vaccines to patients receiving pharmacologic [immunosuppressant] doses of glucocorticoids may potentiate replication of the vaccine virus, thereby increasing the risk of the patient's developing the viral disease, and/or decreasing the patient's antibody response to the vaccine and is not recommended; 4, 6 the patient's immunologic status should be evaluated prior to administration of a live virus vaccine; also, immunization with oral poliovirus vaccine should be postponed in persons in close contact with the patient, especially family members)

(other immunizations are not recommended in patients receiving pharmacologic [immunosuppressant] doses of glucocorticoids because of the increased risk of neurological complications and the possibility of decreased or absent antibody response 3, 20, 21, 46, 50, 58)

(immunizations may be administered to patients receiving glucocorticoids via routes or in quantities that are not likely to cause immunosuppression, for example, those receiving local injections, short-term [less than 2 weeks] therapy, or physiologic doses 20, 33, 36, 42, 47)

Laboratory value alterations

The following have been selected on the basis of their potential clinical significance (possible effect in parentheses where appropriate)¾not necessarily inclusive (>> = major clinical significance):With results of dexamethasone suppression tests

Due to other medications

Alcohol (chronic abuse) or

Glutethimide or

Meprobamate or

Methaqualone or

Methyprylon

(may cause false-positive results in test for endogenous depression)

Benzodiazepines (high doses) or

Cyproheptadine (high doses) or

Glucocorticoid therapy, long-term or

Indomethacin 6, 33

(may cause false-negative results in test for endogenous depression 6, 33)

Ephedrine 6, 33 or

Estrogens (high doses) or

Hepatic enzyme-inducing agents 6, 33 (see Appendix II)

(may cause false-positive results in tests for Cushing's disease or endogenous depression)

Due to medical problems or conditions

Adrenal hyperfunction (Cushing's disease) or

Anorexia nervosa or malnutrition leading to extreme weight loss, recent or

Carcinoma, disseminated, with concurrent serious infection or

Cardiac failure or

Dehydration or

Diabetes mellitus, unstable or

Fever or

Hypertension or

Pregnancy or

Renal failure or

Temporal lobe disease

(may cause false-positive results in test for endogenous depression)

Adrenal insufficiency or

Hypopituitarism

(may cause false-negative results in test for endogenous depression)

Psychiatric disorders such as acute psychosis, mania, chronic schizophrenia, and primary degenerative dementia

(may interfere with results of test for endogenous depression)

With other diagnostic test results

Brain imaging using sodium pertechnetate Tc 99m, technetium Tc 99m gluceptate, or technetium Tc 99m pentetate

(uptake of these diagnostic aids into cerebral tumors may be decreased in patients receiving large doses of glucocorticoids because of glucocorticoid-induced reduction of peritumor edema)

Gonadorelin test for hypothalamic-pituitary-gonadal axis function

(glucocorticoids may alter the results of the gonadorelin test by affecting pituitary secretion of gonadotropins through a complicated feedback mechanism)

Nitroblue-tetrazolium test 4, 6, 10, 30, 33, 50

(false-negative test results may occur 4, 6, 10, 30, 33, 50)

Protirelin test for thyroid function

(physiologic doses of corticosteroids have no effect, but pharmacologic doses may reduce the thyroid-stimulating hormone [TSH] response to protirelin; however, withdrawal of corticosteroids in patients with known hypopituitarism is generally not recommended)

Skeletal imaging using technetium Tc 99m medronate, technetium Tc 99m oxidronate, or technetium Tc 99m pyrophosphate

(long-term use of glucocorticoids may induce bone calcium depletion, thus causing decreased bone uptake of these diagnostic aids)

Skin tests, 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58 including tuberculin and histoplasmin skin tests and patch tests for allergy

(reactions may be suppressed, 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58 especially with daily administration of large doses of corticosteroids)

Thyroid 123I or 131I uptake 20

(may be decreased 20)

With physiology/laboratory test values

Calcium, serum 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58

(concentrations may be decreased 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58)

Glucose, blood and urine

(concentrations may be increased because of intrinsic hyperglycemic activity)

>> Hypothalamic-pituitary-adrenal (HPA) axis function as assessed by:

Adrenocorticotrophic hormone (ACTH, corticotropin) or

Cortisol, blood or

Cortisol, urine or

17-Hydroxycorticosteroids, urine (17-OHCS) or

17-Ketosteroids, total, urine (17-KS)

(may be decreased with pharmacologic doses of glucocorticoids, especially in children)

Lipid profile

(concentrations may be increased)

Platelet count

(may be increased or decreased)

Polymorphonuclear leukocyte count

(may be increased)

Potassium, serum 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58

(concentrations may be decreased because of increased potassium excretion, 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58 especially with agents having significant mineralocorticoid activity)

Sodium, blood 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58

(concentrations may be increased because of sodium retention, 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58 especially with glucocorticoids having significant mineralocorticoid activity)

Uric acid, serum

(concentrations may be increased in patients with acute leukemia but may be decreased in other patients because of weak uricosuric effect)

White blood count

(may be decreased)

Medical considerations/Contraindications

The medical considerations/contraindications included have been selected on the basis of their potential clinical significance (reasons given in parentheses where appropriate)¼ not necessarily inclusive (>> = major clinical significance).
See also Laboratory value alterations.

Note: The medical problems listed below apply only to pharmacologic (supraphysiologic) doses of glucocorticoids, unless otherwise stated.
Except under special circumstances, these medications should not be used when the following medical problems exist

For intra-articular injection

>> Arthroplasty of joint, prior

(increased risk of infection)

>> Blood clotting disorders

(risk of intra- and extra-articular hemorrhage)

>> Fracture, intra-articular

(healing may be retarded)

>> Infection, periarticular, current 47, 50 or history of 50

(may be exacerbated or reactivated)

>> Osteoporosis, juxta-articular, non-arthritis

(may be exacerbated)

>> Unstable joint 10, 26, 50

For neonatal respiratory distress syndrome prophylaxis

>> Amnionitis

>> Bleeding, uterine

>> Febrile illness or infection, especially tuberculosis, maternal or

>> Herpes simplex type 2 infection, active, maternal or

>> Keratitis, viral, maternal

(may be exacerbated; if corticosteroid administration is essential, appropriate antimicrobial therapy must be administered concurrently)

>> Placental insufficiency

>> Premature membrane rupture

(increased risk of maternal infection; the glucocorticoid should be administered immediately if this occurs, since the risk of infection increases with time)

Risk-benefit should be considered when the following medical problems exist

For all indications

>> Acquired immunodeficiency syndrome (AIDS) or 77

>> Human immunodeficiency virus (HIV) infection 77, 79

(although pharmacologic doses of corticosteroids can be effective in the treatment of certain HIV-related diseases, careful medical evaluation of the risks and benefits of this therapy must be done, due to the possible increased risk of severe uncontrollable infections and/or neoplasms; 73, 77, 79 in one study in patients given tapering doses of intravenous methylprednisolone starting with 60 mg every 6 hours for 8 days as an adjunct to antipneumocystis therapy, an increase in frequency or severity of life-threatening opportunistic infections was observed; 68, 76, 77 in a study of similar patients given tapering doses of prednisone starting at 40 mg two times a day for 21 days, no increase in the incidence of Kaposi's sarcoma or life-threatening opportunistic infections was observed, though the incidence of oral candidiasis and mucocutaneous herpes simplex infection did increase 68, 71, 77)

>> Anastomoses, intestinal, recent 3, 4, 6, 10, 18, 20, 21, 29, 30, 33, 36, 42, 46, 47, 50, 58

(corticosteroids should be used with caution 3, 4, 6, 10, 18, 20, 21, 29, 30, 33, 36, 42, 46, 47, 50, 58)

>> Cardiac disease 20, 29 or

>> Congestive heart failure 50, 58 or

Hypertension 3, 4, 6, 10, 18, 20, 21, 29, 30, 33, 36, 42, 46, 47, 50, 58 or

>> Renal function impairment or disease, severe

(edema may be hazardous, especially with agents having significant mineralocorticoid activity)
(patients undergoing dialysis may have increased risk of avascular necrosis with long-term corticosteroid use)

>> Chickenpox, existing or recent (including recent exposure) 3, 4, 6, 10, 18, 20, 21, 29, 33, 36, 46, 50, 58 or

>> Measles, existing or recent (including recent exposure) 3, 4, 6, 10, 18, 20, 21, 29, 33, 36, 46, 50

(risk of severe, potentially fatal, generalized disease; 4, 6, 10, 18, 20, 21, 33, 36, 46, 50 extra care to avoid exposure to these infections is recommended; 4, 10, 18, 20, 21, 33, 36, 46, 50 prophylactic therapy with varicella zoster immune globulin [VZIG] or immune globulin intravenous [IGIV] or intramuscular [IGIM], as appropriate, may be indicated in exposed patients; 3, 4, 6, 10, 18, 20, 21, 29, 33, 36, 46, 50, 58 therapy with an antiviral agent may be indicated if chickenpox develops 3, 4, 6, 10, 18, 20, 21, 29, 33, 36, 46, 50)

Colitis, ulcerative, nonspecific, with possibility of impending perforation, abscess, or other infection 3, 4, 6, 10, 18, 20, 21, 29, 30, 33, 36, 42, 46, 47, 50, 58 or

Diverticulitis 3, 4, 6, 10, 18, 20, 21, 29, 30, 33, 36, 42, 46, 47, 50, 58 or

>> Esophagitis, gastritis, or peptic ulcer, active or latent 3, 4, 6, 10, 18, 20, 21, 29, 30, 33, 36, 42, 46, 47, 50, 58

(symptoms of progression or reactivation may be masked; 36, 42, 47, 50 hemorrhage and/or perforation may occur without warning 36, 42, 47, 50)

>> Diabetes mellitus or predisposition to 3, 4, 20, 29, 30, 58

(may be exacerbated or activated 3, 4, 29, 30, 58)

>> Fungal infections, systemic 3, 4, 6, 18, 20, 21, 30, 33, 36, 42, 46, 47

(may be exacerbated; pharmacologic doses of corticosteroids should not be given unless the patient is concurrently receiving an antifungal agent)

Glaucoma, 3, 29, 30, 33, 58 open-angle

(intraocular pressure may be increased 3, 29, 30, 33, 58)

Hepatic function impairment or disease 29

(increased risk of glucocorticoid toxicity, especially if hypoalbuminemia is present; possibility of impaired conversion of cortisone or prednisone to their active metabolites, although this effect may be offset by decreased protein binding or clearance and/or conversion in other tissues)

>> Herpes simplex, ocular 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58

(possible corneal perforation 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58)

Herpetic lesions, oral

Hyperlipidemia

(concentrations of fatty acids or cholesterol may be increased)

Hypersensitivity to corticosteroids 18, 20, 36, 42, 47

Hyperthyroidism 29

(glucocorticoid effect may be impaired because of accelerated metabolism; this may be especially important with physiologic doses or low pharmacologic doses)

Hypoalbuminemia or conditions predisposing to, including hepatic cirrhosis 3, 4, 6, 10, 18, 20, 21, 29, 30, 33, 36, 42, 46, 47, 50, 58 or nephrotic syndrome

(increased risk of toxicity because reduced availability of albumin for glucocorticoid binding leads to increased serum concentration of unbound drug; reduction in initial dosage is recommended)

Hypothyroidism 3, 4, 6, 10, 18, 20, 21, 29, 30, 33, 36, 42, 46, 47, 50, 58

(decreased metabolism of corticosteroid may result)

Infections, viral or bacterial, uncontrolled, local or systemic 6, 10, 18, 20, 21, 29, 30, 33, 36, 42, 46, 47, 50

(symptoms of infection may be masked; new infection may develop; resistance and ability to localize infection may be decreased; if infection occurs during therapy, appropriate antimicrobial therapy should be instituted 3, 4, 6, 10, 18, 21, 29, 30, 33, 36, 42, 46, 47, 50, 58)

>> Myasthenia gravis 3, 4, 6, 10, 18, 20, 21, 29, 30, 33, 36, 42, 46, 47, 50, 58

(muscle weakness may be increased initially, possibly leading to respiratory distress; 18, 20 the patient should be hospitalized, and respiratory support should be immediately available, when glucocorticoid therapy is initiated)

>> Myocardial infarction, recent 4, 6, 10, 30, 33

(possible risk of left ventricular free wall rupture; extreme caution is recommended 4, 6, 10, 30, 33)

Osteoporosis 3, 4, 6, 10, 18, 20, 21, 29, 30, 33, 42, 46, 47, 50, 58

(may be exacerbated 50, 58)

>> Psychosis, acute 3, 6, 10, 18, 20, 21, 29, 30, 33, 36, 42, 46, 47, 50

(may be aggravated 3, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50)

Renal function impairment, 4, 29, 30 mild to moderate, or stones

(fluid retention may exacerbate these conditions; increased risk of edema, especially with agents having mineralocorticoid activity)

(patients receiving dialysis may have increased risk of avascular necrosis with long-term corticosteroid use)

>> Strongyloides infestation, confirmed or suspected 3, 4, 6, 10, 18, 33, 36, 50

(corticosteroid-induced immunosuppression may lead to hyperinfection and dissemination with widespread larval migration, often accompanied by severe enterocolitis and potentially fatal gram-negative septicemia 3, 4, 6, 10, 18, 36, 50)

Systemic lupus erythematosus (SLE)

(cautious use is recommended because of an increased risk of aseptic necrosis)

>> Tuberculosis, active, 4, 6, 18, 20, 21, 29, 33, 36, 46, 47, 50 positive skin test, latent, or history of 3, 10, 30, 42, 50, 58

(may be exacerbated or reactivated; appropriate antitubercular chemotherapy or prophylaxis should be administered concurrently 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58)

Patient monitoring

The following may be especially important in patient monitoring (other tests may be warranted in some patients, depending on condition; >> = major clinical significance):

Adrenal function assessment, 29 may include adrenocorticotrophic hormone (ACTH) stimulation test, blood or urine cortisol concentrations, urine 17-hydroxycorticosteroids concentration, or urine 17-ketosteroids concentration

(may be required during, and following withdrawal of high-dose or long-term [more than 3 weeks] therapy to assess adrenal function; complete recovery of adrenal function may require up to 1 year following prolonged use, especially with high doses; in some patients receiving prolonged, high-dose therapy, complete recovery may never occur)

Electrolytes, serum and

Occult blood, stool

(may be required during long-term therapy)

Glucose concentrations, blood or urine 18, 20, 30, 34 or

Glucose tolerance test

(may be required for patients with diabetes mellitus or a predisposition to diabetes mellitus 30)

Growth and development determinations 3, 4, 6, 10, 18, 20, 21, 30, 33, 46, 50, 58

(recommended in children and adolescents receiving prolonged therapy 3, 4, 6, 10, 18, 20, 21, 30, 33, 46, 50, 58)

Ophthalmologic examinations

(may be required at periodic intervals for adults or children receiving therapy for more than 6 weeks to detect the presence of cataracts, glaucoma, increased intraocular pressure, or ocular infections)

Prothrombin time (PT) 4, 6, 10, 30, 33

(frequent monitoring recommended in patients receiving coumarin anticoagulants concurrently 4, 6, 10, 30, 33)

Side/Adverse Effects

Note: The risk of adverse effects with pharmacologic doses of corticosteroids generally increases with the duration of therapy and frequency of administration and, to a lesser extent, with dosage. Chronic administration of physiologic replacement doses of corticosteroids rarely causes adverse effects.

Administration of glucocorticoids via local injection reduces the risk of systemic effects. The risk of both systemic and local adverse effects is still present to a degree, however, and increases with the frequency of injections.

Pharmacologic doses of glucocorticoids lower resistance to infection; the patient may be predisposed to systemic infections during, and for a time following, therapy. Increased susceptibility to infection may occur with short-term high-dose use ("pulse" therapy) as well as with more prolonged use. Also, symptoms of onset or progression of infections may be masked.

The following side/adverse effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate)^{3/4}not necessarily inclusive:

Those indicating need for medical attention

Incidence less frequent

Diabetes mellitus (decreased or blurred vision; frequent urination; increased thirst) 4, 6, 10, 18, 20, 21, 29, 30, 33, 36, 42, 46, 47, 50, 58

Incidence rare

Burning, numbness, pain, or tingling at or near injection site 8, 33; congestive heart failure^{3/4}in susceptible individuals 10, 18, 20, 21, 33, 36, 42, 46, 50; generalized allergic reaction (skin rash or hives) 4, 10, 29, 33, 36, 42, 47, 50; local allergic reaction or infection at injection site (redness, swelling, pain, or other signs of infection or allergic reaction); psychic disturbances such as delirium (confusion;

excitement; restlessness); disorientation ; euphoria (false sense of well-being); hallucinations (seeing, hearing, or feeling things that are not there); manic-depressive episodes (sudden, wide mood swings); mental depression, or paranoia (mistaken feelings of self-importance or being mistreated) 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 58; sudden blindness 3, 4, 8, 9, 10, 30, 33, 50

Note: Psychic disturbances are more likely to occur in patients with chronic debilitating illnesses that predispose them to psychic disturbances and in patients receiving higher daily dosages. Psychic disturbances may be related to dose rather than duration of therapy; symptoms may appear within a few days to 2 weeks after initiation of therapy and usually are associated with doses equivalent to 40 mg or more of prednisone per day. Additionally, euphoria or fear of relapse may lead to psychological dependence or abuse of corticosteroids.

Sudden blindness following injection into sites in the head or neck area, 8, 9, 10, 30, 33, 50 such as nasal turbinates or scalp, is due to possible entry of drug crystals into ocular blood vessels.

With intravenous administration

Anaphylaxis, generalized (hives; shortness of breath ; swelling of face, nasal membranes, and eyelids; tightness in chest; troubled breathing; wheezing) 10, 18, 33, 36, 42, 47, 50; cardiac arrhythmias 18, 50; flushing of face or cheeks; seizures 10, 18, 20, 21, 33, 36, 42, 46, 47, 50

Note: Rapid intravenous administration of high doses of corticosteroids has been reported to cause angioedema and/or anaphylactic reactions, seizures, and sudden death associated with cardiac arrhythmias. 18 Monitoring of the electrocardiogram (ECG) is recommended. Equipment, medications, and trained personnel necessary for treating these complications should be immediately available.

Those occurring principally during long-term use indicating need for medical attention

Acne 50; adrenal suppression 4, 6, 10, 18, 21, 30, 33, 36, 42, 46, 47, 50, 58; avascular necrosis (hip or shoulder pain); cataracts, posterior subcapsular (gradual blurring or loss of vision) 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58; Cushing's syndrome effects including filling or rounding out of the face; hirsutism (unusual increase in hair growth); hypertension; menstrual irregularities; muscle weakness; or striae (reddish purple lines on arms, face, legs, trunk, or groin) 3, 4, 6, 10, 18, 20, 21, 29, 30, 33, 36, 42, 46, 47, 50, 58; cutaneous or subcutaneous tissue atrophy (thin, shiny skin; pitting or depression of skin at injection site)¼with frequent repository injections 3, 4, 9, 10, 18, 30, 33, 50; ecchymosis (unusual bruising) 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58; fluid and sodium retention (rapid weight gain; swelling of feet or lower legs) 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58; glaucoma with possible damage to optic nerves (blurred vision or other change in vision; eye pain) 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58; growth suppression¼in children 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58; hypokalemic syndrome (irregular heartbeat; muscle cramps or pain; unusual tiredness or weakness) 3, 4, 6, 10, 18, 20, 21, 30, 36, 42, 46, 47, 50, 58; impaired wound healing 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58; increased intracranial pressure (headache; insomnia; papilledema; unusual tiredness or weakness) 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58; ocular infection, secondary, fungal or viral (blurred vision or other change in vision; eye pain ; redness of eyes; sensitivity of eyes to light; tearing) 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58; osteoporosis or bone fractures (pain in back, ribs, arms, or legs)¼includes vertebral compression and long bone pathologic fractures 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58; pancreatitis (continuing abdominal or stomach pain or burning; nausea; vomiting) 3, 4, 6, 10, 18, 21, 30, 33, 36, 42, 46, 47, 50, 58; peptic ulceration or intestinal perforation (bloody or black, tarry stools; continuing abdominal or

stomach pain or burning) 3, 4, 6, 10, 18, 20, 21, 29, 30, 33, 36, 42, 46, 47, 50, 58; scarring at injection site ; steroid myopathy (muscle weakness) 3, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58; tendon rupture 6, 10, 18, 33, 36, 42, 47; thin, fragile skin 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58

Those indicating need for medical attention only if they continue or are bothersome

Incidence more frequent

Gastrointestinal irritation (nausea; vomiting) 6, 10, 18, 30, 33; increased appetite 4, 6, 10, 30, 33; indigestion 29; nervousness or restlessness ; trouble in sleeping 50; weight gain 10

For triamcinolone

Loss of appetite

Incidence less frequent or rare

Changes in skin color or hypopigmentation (darkening or lightening of skin color) 4, 9, 10, 18, 30, 33, 50; dizziness or lightheadedness; flushing of face or cheeks 20, 46, 47, 50; headache 3, 4, 6, 10, 18, 20, 21, 30, 33, 36, 46, 47, 50, 58; hiccups 6, 9, 33; increased joint pain following intra-articular injection; increased sweating 1, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 16, 18, 19, 20, 21, 30, 33, 36, 42, 46, 47, 50, 58; nosebleeds following intranasal injection; vertigo (dizziness; sensation of spinning) 4, 6, 10, 18, 20, 21, 30, 33, 36, 46, 47, 50, 58

Note: Hypopigmentation is more likely at the injection site.

Flushing of face or cheeks may persist for 24 to 48 hours.

Increased joint pain may occur within a few hours postinjection and persist for up to 48 hours.

Those occurring principally after medication is discontinued, indicating a corticosteroid withdrawal syndrome and the need for medical attention

Withdrawal syndrome (abdominal or back pain; dizziness ; fainting; frequent or continuing unexplained headaches; low-grade fever 4, 6, 10, 20, 30, 33; muscle or joint pain 4, 6, 10, 20, 30, 33; nausea; prolonged loss of appetite; rapid weight loss; reappearance of disease symptoms; shortness of breath; unusual tiredness or weakness 4, 6, 10, 20, 30, 33; vomiting)

Note: Too-rapid withdrawal of therapy, especially after prolonged use, may cause acute, possibly life-threatening, adrenal insufficiency and/or a withdrawal syndrome not related to hypothalamic-pituitary-adrenal (HPA) axis suppression.

Patient Consultation

As an aid to patient consultation, refer to Advice for the Patient, Corticosteroids Glucocorticoid Effects (Systemic) .

In providing consultation, consider emphasizing the following selected information (>> = major clinical significance):

Before using this medication

>> Conditions affecting use, especially:

Hypersensitivity to corticosteroids

Pregnancy%Pharmacologic doses in animals show some evidence of increased risk of placental insufficiency, decreased birthweight, or stillbirths; other animal studies show increased incidence of cleft palate, placental insufficiency, spontaneous abortions, and intrauterine growth retardation

Breast-feeding%Breast-feeding is not recommended during use of higher pharmacologic doses

Use in children%Infants born to women who received corticosteroids during pregnancy should be monitored for signs of hypoadrenalism; close monitoring also is required during chronic therapy because suppression of growth and development may result; possible increased severity of chickenpox or measles in children receiving immunosuppressant doses; increased risk for developing osteoporosis, avascular necrosis of the femoral heads, glaucoma, or cataracts during prolonged therapy

Use in the elderly%Increased risk for developing osteoporosis (especially in postmenopausal females) or hypertension

Other medications, especially aminoglutethimide; amphotericin B, parenteral; antacids; antidiabetic agents, oral; cyclosporine; digitalis glycosides; diuretics; hepatic enzyme-inducing agents; insulin; mitotane; potassium supplements; ritodrine; sodium-containing medications; somatrem; somatropin; or vaccines, live virus, or other immunizations

Other medical problems, especially

For all uses%Acquired immunodeficiency syndrome (AIDS); anastomoses, intestinal, recent; cardiac disease; chickenpox; congestive heart failure; diabetes mellitus; esophagitis, gastritis, or peptic ulcer; fungal infections, systemic; herpes simplex, ocular; human immunodeficiency virus (HIV) infection; measles; myasthenia gravis; myocardial infarction, recent; psychosis, acute; renal function impairment or disease; Strongyloides infestation; or tuberculosis

For intra-articular injection only%Arthroplasty of joint, blood clotting disorders, intra-articular fracture, osteoporosis, periarticular infection, or unstable joint

For neonatal respiratory distress syndrome prophylaxis only%Amnionitis, febrile illness or infection, herpes simplex type 2 infection, maternal viral keratitis, placental insufficiency, premature membrane rupture, or uterine bleeding

Proper use of this medication

For oral dosage forms

>> Taking with food to minimize gastrointestinal irritation

Possibility that alcohol may enhance ulcerogenic effects of medication

For budesonide capsules (micronized)

Swallowing capsules whole without breaking, crushing, or chewing 29

>> Importance of not using more medication than the amount prescribed

>> Proper dosing

Missed dose: If dosing schedule is%

Every other day: Taking as soon as possible if remembered same morning; if remembered later, not taking until next morning, then skipping a day

Once a day: Taking as soon as possible; not taking if almost time for next dose; not doubling doses

Several times a day: Taking as soon as possible; doubling if time for next dose

>> Proper storage

Precautions while using this medication

>> Regular visits to physician to check progress during and following therapy

>> Checking with physician before discontinuing medication; gradual dosage reduction may be necessary

Checking with physician if symptoms recur or worsen when dose decreased or therapy discontinued

For patients on long-term therapy

>> Possible need for sodium restriction or potassium supplementation

Possible need for calorie restriction

Possible need for increased protein intake

Possible need for ophthalmologic examinations

Carrying medical identification card indicating use of corticosteroids

>> Caution in receiving skin tests

>> Caution if any kind of surgery or emergency treatment is required

>> Caution if serious infections or injuries occur

>> Avoiding exposure to chickenpox or measles (especially for children); telling physician right away if exposure occurs

>> Caution in receiving vaccinations or other immunizations or coming in contact with persons receiving oral poliovirus vaccine

For patients with diabetes: May increase blood glucose concentrations

For parenteral dosage forms

Restricting use of joint following intra-articular injection

Checking with physician if redness or swelling occurs and continues or becomes worse following local injection

Side/adverse effects

Signs of potential side effects, especially diabetes mellitus; burning, numbness, pain, or tingling at or near injection site; congestive heart failure (in susceptible individuals); generalized allergic reaction; local allergic reaction or infection at injection site; psychic disturbances; sudden blindness; anaphylaxis,

generalized; cardiac arrhythmias; flushing of face or cheeks; seizures; acne; adrenal suppression; avascular necrosis; cataracts, posterior subcapsular; Cushing's syndrome effects; cutaneous or subcutaneous tissue atrophy; ecchymosis; fluid and sodium retention; glaucoma with possible damage to optic nerves; growth suppression (in children); hypokalemic syndrome; impaired wound healing; increased intracranial pressure; ocular infection, secondary, fungal or viral; osteoporosis or bone fractures; pancreatitis; peptic ulceration or intestinal perforation; scarring at injection site; steroid myopathy; tendon rupture; and thin, fragile skin

General Dosing Information

See Table 3.

For replacement therapy in chronic adrenocortical insufficiency states, corticosteroid therapy must be continued for the life of the patient. It is recommended that dosage of cortisone or hydrocortisone be timed to simulate endogenous corticosteroid secretion, with two thirds of the daily dose administered in the morning and one third in the evening. Other corticosteroids usually are given once a day.

For treatment of congenital adrenal hyperplasia, suppression of corticotropin secretion is required to decrease hypersecretion of adrenal androgens. This usually is achieved by administering one third of the daily dose of cortisone or hydrocortisone in the morning and two thirds in the evening or giving one third of the daily dose three times a day at evenly spaced intervals. Other corticosteroids usually are given once a day.

Except in severe conditions or emergency situations, it is recommended that therapy be instituted with low doses that are increased as necessary to provide the desired effect. 3, 4, 6, 11, 12, 20, 21, 30, 46, 47 For most conditions, administration in the lowest effective dose for the shortest time possible is recommended. Dosage requirements are variable and should be individualized according to the disease being treated and patient response 6, 7, 8, 9, 10, 11, 12, 19, 20, 21, 25, 27, 28, 30, 31, 33, 34, 36, 40, 41, 42, 44, 46, 47, 48, 50, 51, 59 rather than by age or body weight. Whenever possible, local administration is recommended in order to concentrate the medication at the affected site and reduce the risk of systemic effects. After a favorable response is obtained, the dosage should be decreased gradually to the lowest dose that will maintain an adequate clinical response. 3, 4, 11, 25, 28, 36, 40, 41, 42, 44, 46, 47, 48, 51, 58

Frequent monitoring of drug effect is required. 19, 20, 46, 40, 44, 47, 48, 51 Situations that may necessitate dosage adjustments include remissions or exacerbations of the disease process and the patient's response to the medication. 20, 25, 44, 47, 48, 51

Clinically significant hypothalamic-pituitary-adrenal (HPA) axis suppression leading to adrenal insufficiency may occur more readily with multiple daily doses or evening administration than with single doses given every morning or every other morning. Administration of a single daily dose of a short- or intermediate-acting corticosteroid prior to 9 a.m. may reduce the risk of HPA axis suppression (because maximum endogenous corticosteroid secretion occurs in the morning) and is recommended for daily administration whenever possible. However, some disease conditions may require multiple daily doses.

Following discontinuation of short-term (up to 5 days) high-dose use, adrenal recovery may occur within 1 week. However, following prolonged high-dose administration, complete recovery of adrenal function may require up to 1 year. Following very prolonged suppression, complete recovery may never occur.

During the recovery period, monitoring of adrenal function may be required to assess the patient's ability to respond to stress.

Patients with confirmed or suspected adrenal insufficiency, including those already receiving replacement therapy, require an increase in dosage or reinstatement of therapy prior to, during, and for a time following, exposure to emotional stress or physical stress such as severe infection, surgery (including dental surgery), or injury. 3, 4, 6, 10, 11, 18, 19, 20, 21, 25, 28, 29, 30, 33, 36, 40, 41, 42, 46, 47, 50, 58 Administration of sodium and/or a mineralocorticoid also may be required. 10, 18, 20, 21, 33, 36, 42, 46, 47, 50 Dosage and duration of such therapy are dependent on the severity of the stress.

When medication is to be discontinued, dosage should be reduced gradually. 4, 6, 10, 11, 18, 19, 20, 21, 25, 28, 30, 33, 36, 40, 41, 42, 43, 44, 46, 47, 48, 59 The rate at which dosage can be decreased and the time required for complete withdrawal of therapy are variable, depending on the specific agent used; dose, frequency, and route of administration; duration of therapy; condition being treated; and patient response.

For oral dosage forms only

If oral long-term use is required for disease therapy, an alternate-day regimen using an intermediate-acting corticosteroid is recommended to minimize HPA axis suppression and possibly other adverse effects. An intermediate-acting corticosteroid is one that suppresses HPA axis activity for 12 to 36 hours following a single dose. Administration of longer-acting corticosteroids on an alternate-day schedule does not reduce the risk of HPA axis suppression and is not recommended.

Alternate-day therapy utilizes a single dose administered every other morning, usually in a quantity equivalent to, or somewhat higher than, twice the usual or pre-established daily dose. The patient should have a normal or moderately responsive HPA axis.

If treatment has been initiated with daily administration, changes to alternate-day therapy should be made gradually, after the patient's condition has stabilized. However, for some diseases, such as childhood nephrotic syndrome, therapy may be initiated with alternate-day dosing.

Alternate-day therapy may not be effective in treating hematologic disorders, malignancies, ulcerative colitis, or severe conditions. Also, some patients, such as those with asthma or rheumatoid arthritis, may experience exacerbation of symptoms on the second day. Administration of (or increasing the dosage of) suitable supplemental therapy on the second day may provide sufficient symptomatic relief to permit alternate-day dosing in some patients.

For parenteral dosage forms only

For acute adrenocortical insufficiency, initiation of corticosteroid therapy by intravenous injection followed by slow intravenous infusion or intramuscular administration is recommended. Certain other acute conditions also may require initiation of therapy with intramuscular or intravenous administration of a rapidly acting formulation.

In severe or life-threatening conditions, single-dose or short-term intravenous administration of a very high dose ("pulse" therapy) may produce the required therapeutic response with a minimum risk of prolonged HPA axis suppression or other adverse effects. Such therapy has been recommended for treating conditions such as organ transplant rejection reactions, acute nephritis associated with systemic lupus erythematosus, vasculitis, adult respiratory distress syndrome, and shock. However, rapid intravenous administration of high doses of corticosteroids has been reported to cause potentially life-threatening side effects and appropriate precautions should be observed.

When the suspension dosage forms are administered intramuscularly, they should be injected deeply into the gluteal muscle to prevent local tissue atrophy. It is recommended that the deltoid muscle not

be used because of a higher incidence of local atrophy. In addition, do not inject repeatedly into the same site.

A standard textbook should be consulted for specific techniques and procedures applicable to local injection of corticosteroids for various indications.

Following intra-articular injection, the injected joint should not be overused, even if pain is relieved, because of the increased risk of joint damage or deterioration. 26, 50 It is recommended that weight-bearing joints be rested for 24 to 48 hours postinjection.

Administration of a local anesthetic concurrently with intra-articular or soft tissue injection of a corticosteroid may reduce the pain of injection and provide immediate relief of symptoms. However, a postinjection flare of pain may occur when the local anesthetic effect subsides.

Dosages for local injections (e.g., intra-articular, intrabursal, intradermal, intralesional) are given as ranges only. The actual dosage depends upon the size of the joint or lesion and the severity of the condition being treated. 10

Diet/Nutrition

Administration of oral dosage forms with food may relieve the indigestion or mild gastrointestinal irritation that may occur. 6

Patients receiving prolonged therapy with pharmacologic doses of corticosteroids, especially those with significant mineralocorticoid activity, may require sodium restriction and/or potassium supplementation during therapy. 3, 4, 6, 10, 18, 21, 30, 33, 36, 42, 50, 58

Because corticosteroids promote protein catabolism, increased protein intake may be necessary during prolonged therapy.

Administration of calcium and vitamin D and, if the patient's condition permits, exercise or physical therapy may reduce the risk of corticosteroid-induced osteoporosis during prolonged therapy.

For treatment of adverse effects

Recommended treatment consists of the following:

- For gastrointestinal effects: Administration of antacids between meals may relieve indigestion or mild gastrointestinal irritation that may occur during parenteral, as well as oral, corticosteroid therapy. However, the efficacy of antacids or other antiulcer medications in preventing severe gastrointestinal problems, such as ulceration, hemorrhage, and/or bowel perforation, during corticosteroid therapy has not been established.
- For mental depression or psychoses: If possible, decrease corticosteroid dosage or discontinue therapy. A phenothiazine may be administered if necessary; lithium also has been recommended. Some patients may require electroconvulsive therapy if severe depression persists. Tricyclic antidepressants should not be used since they do not relieve, and may exacerbate, corticosteroid-induced mental disturbances. Prophylactic administration of an antipsychotic agent may be indicated if additional courses of corticosteroid therapy are required by a patient with a history of corticosteroid-induced psychosis.
- For withdrawal effects (non-HPA axis suppression): Administration of aspirin or another nonsteroidal anti-inflammatory drug may alleviate some of the symptoms of this condition.

BETAMETHASONE

Summary of Differences

Precautions: Pediatrics Not recommended for chronic use; especially likely to inhibit growth.

Oral Dosage Forms

BETAMETHASONE SYRUP USP

Usual adult and adolescent dose

Corticosteroid

Oral, 0.6 to 7.2 mg a day as a single dose or in divided doses. 1, 27

Usual pediatric dose

Adrenocortical insufficiency

Oral, 0.018 mg per kg of body weight or 0.5 mg per square meter of body surface area a day in three divided doses.

Other indications

Oral, 0.063 to 0.25 mg per kg of body weight or 1.88 to 7.5 mg per square meter of body surface area a day in three or four divided doses.

Strength(s) usually available

U.S. 0.6 mg per 5 mL (Rx) [Celestone (alcohol <1%) (sodium chloride) (sorbitol) (sugar) 1]

Canada Not commercially available.

Packaging and storage:

Store between 2 and 30 °C (36 and 86 °F), 1 protected from light. 1 Store in a well-closed container. 57
Protect from freezing.

BETAMETHASONE TABLETS USP

Usual adult and adolescent dose

See Betamethasone Syrup USP.

Usual pediatric dose

See Betamethasone Syrup USP.

Strength(s) usually available

U.S. 0.6 mg (Rx) [Celestone (scored) 27]

Canada Not commercially available. 38

Packaging and storage:

Store between 2 and 30 °C (36 and 86 °F) 27 in a well-closed container. 57

Note: Protect the 21-tablet pack from excessive moisture. 27

BETAMETHASONE SODIUM PHOSPHATE EFFERVESCENT TABLETS

Usual adult and adolescent dose

Corticosteroid¾

Oral, 0.25 to 1 mg three or four times a day. 58

Usual pediatric dose

See Betamethasone Syrup USP.

Strength(s) usually available

U.S.¾Not commercially available.

Canada¾0.5 mg (Rx)[Betnesol (scored) 58]

Packaging and storage:

Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), in a well-closed container, unless otherwise specified by manufacturer. Protect from moisture.

Preparation of dosage form:

Dissolve in water immediately prior to ingestion.

Note: When dispensing, explain dissolution requirement to patient.

BETAMETHASONE SODIUM PHOSPHATE EXTENDED-RELEASE TABLETS

Usual adult and adolescent dose

Corticosteroid¾

Oral, 2 to 6 mg a day initially, then adjusted according to patient response.

Usual pediatric dose

See Betamethasone Syrup USP.

Strength(s) usually available

U.S.¼Not commercially available.
Canada¼Not commercially available. 38

Packaging and storage:

Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), in a well-closed container, unless otherwise specified by manufacturer.

Parenteral Dosage Forms

BETAMETHASONE SODIUM PHOSPHATE INJECTION USP

Note: The dosing and strengths of the dosage forms available are expressed in terms of betamethasone base (not the sodium phosphate salt).

Usual adult and adolescent dose

Corticosteroid¼

Intra-articular, intralesional, or soft-tissue injection, up to 9 mg (base), repeated as needed. 2

Intramuscular or intravenous, up to 9 mg a day. 2

Usual pediatric dose

Adrenocortical insufficiency¼

Intramuscular, 0.018 mg (base) per kg of body weight or 0.5 mg per square meter of body surface area a day (in three divided doses) every third day; or 0.0058 to 0.0088 mg per kg of body weight or 0.17 to 0.25 mg per square meter of body surface area once a day.

Other indications¼

Intramuscular, 0.021 to 0.13 mg per kg of body weight or 0.63 to 3.75 mg per square meter of body surface area every twelve to twenty-four hours.

Strength(s) usually available

U.S.¼3 mg (base) (4 mg sodium phosphate) per mL (Rx)[Celestone Phosphate (sodium bisulfite 3.2 mg)]
[Selestoject (sodium bisulfite)] [Generic]

Canada¼Not commercially available.

Packaging and storage:

Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), protected from light, unless otherwise specified by manufacturer. Protect from freezing.

BETAMETHASONE SODIUM PHOSPHATE AND BETAMETHASONE ACETATE INJECTABLE SUSPENSION USP
15

Usual adult and adolescent dose

Arthritis, gouty, acute or
Bursitis, acute or subacute or
Tenosynovitis, nonspecific acute^{3/4}
Intrabursal or intramuscular, 1.5 to 6 mg, repeated every three to seven days, 3 or as needed. 3, 39

Arthritis, rheumatoid or
Osteoarthritis, post-traumatic^{3/4}
Intra-articular, 1.5 to 12 mg, depending upon the size of the affected joint, repeated as needed. 3, 39

Asthma, bronchial or
Rhinitis, allergic, perennial or seasonal^{3/4}
Intramuscular, 6 to 12 mg once a week. 39

Dermatologic disorders^{3/4}
Intradermal, 1.2 mg per square centimeter of affected skin 3, 39 every three to seven days. 39

Status asthmaticus or
Lupus erythematosus, disseminated^{3/4}
Intramuscular, initially 12 mg. 39

Usual adult and adolescent prescribing limits

Dermatologic disorders^{3/4}
6 mg per week. 3, 39

Usual pediatric dose

Dosage has not been established.

Strength(s) usually available

U.S.^{3/4}6 mg (3 mg of betamethasone acetate and 3 mg of betamethasone base) per mL (Rx)[Celestone Soluspan 3]

Canada^{3/4}6 mg (3 mg of betamethasone acetate and 3 mg of betamethasone base) per mL (Rx)[Celestone Soluspan 39]

Packaging and storage:

Store between 2 and 25 °C (36 and 77 °F), protected from light, 3, 39 unless otherwise specified by manufacturer. Protect from freezing.

Incompatibilities:

This medication should not be mixed with parenteral-local anesthetic formulations containing parabens, phenol, or other such preservatives, because flocculation of the corticosteroid may occur. 3

The required quantity of corticosteroid suspension should be drawn into the syringe first, then the local anesthetic added. Do not introduce the local anesthetic directly into the multiple-dose vial. 3

Auxiliary labeling:

- Shake well. 3, 39

Additional dosing information

For administration of injections, see manufacturer's labeling.
Do not administer this medication intravenously. 3

BUDESONIDE

Oral Dosage Forms

BUDESONIDE EXTENDED-RELEASE CAPSULES (MICRONIZED)

Usual adult dose

Crohn's disease^{3/4}

Active disease: Oral, 9 mg once a day in the morning before breakfast for up to eight weeks. 29

Maintenance of remission: Oral, 6 mg once a day in the morning before breakfast. 29

Usual pediatric dose

Safety and efficacy have not been established. 29

Usual geriatric dose

See Usual adult dose.

Strength(s) usually available

U.S.^{3/4}Not commercially available.

Canada^{3/4}3 mg (Rx)[Entocort 29]

Packaging and storage:

Store between 15 and 30 °C (59 and 86 °F), 29 unless otherwise specified by manufacturer. Store in a tight container. 29

Auxiliary labeling:

Store in original container. 29

Note: Dispense in original container. 29

CORTISONE

Oral Dosage Forms

CORTISONE ACETATE TABLETS USP

Usual adult and adolescent dose

Corticosteroid^¾

Oral, 25 to 300 mg a day as a single dose or in divided doses. 5, 31, 59

Usual pediatric dose

Adrenocortical insufficiency^¾

Oral, 0.7 mg per kg of body weight or 20 to 25 mg per square meter of body surface area a day in divided doses.

Other indications^¾

Oral, 2.5 to 10 mg per kg of body weight or 75 to 300 mg per square meter of body surface area a day as a single dose or in divided doses.

Strength(s) usually available

U.S.^¾5 mg (Rx) [Generic] (scored) (lactose)

10 mg (Rx) [Generic] (scored)

25 mg (Rx)[Cortone Acetate (scored) 5] [Generic] (scored) 59

Canada^¾5 mg (Rx)[Cortone 31]

25 mg (Rx)[Cortisone Acetate-ICN (scored) 56] [Cortone (scored) 31] [Generic]

Packaging and storage:

Store between 15 and 30 °C (59 and 86 °F) 59 , unless otherwise specified by manufacturer. Store in a well-closed container. 57 Protect from light. 59

Parenteral Dosage Forms

CORTISONE ACETATE INJECTABLE SUSPENSION USP 15

Usual adult and adolescent dose

Corticosteroid^¾

Intramuscular, 20 to 300 mg a day. 4, 30

Usual pediatric dose

Adrenocortical insufficiency¼

Intramuscular, 0.7 mg per kg of body weight or 37.5 mg per square meter of body surface area a day every third day; or 0.23 to 0.35 mg per kg of body weight or 12.5 mg per square meter of body surface area once a day.

Other indications¼

Intramuscular, 0.83 to 5 mg per kg of body weight or 25 to 150 mg per square meter of body surface area every twelve to twenty-four hours.