ANABOLIC STEROIDS (Systemic)

Introduction

This monograph includes information on the following:1) Nandrolone ; 2) Oxandrolone b; 3) Oxymetholone ; 4) Stanozolol b.

VA CLASSIFICATION (Primary/Secondary)
Nandrolone¾HS101/AN900; BL400
Oxandrolone¾HS101
Oxymetholone¾HS101/; IM900
Stanozolol¾HS101/; IM900

Note: Controlled substance classification¾U.S.¾Schedule III 3, 860

Commonly used brand name(s):Anadrol-503; Anapolon 503; Deca-Durabolin1; Durabolin1; Durabolin-501; Hybolin Decanoate1; Hybolin-Improved1; Kabolin1; Oxandrin2; Winstrol4.

Category

Note: All anabolic steroids are approximately equal in efficacy. 823, 829, 833 Selection of a particular generic substance or dosage form is dependent upon the incidence of side effects, preferred route of administration, or the duration of action desired. 823, 829, 833 Indications listed for individual generic products included are based on currently marketed product labeling.Anabolic steroid¾Nandrolone; Oxandrolone; Oxymetholone; Stanozolol.

Antianemic¾Nandrolone; Oxymetholone; Stanozolol.

Antineoplastic¾Nandrolone.

Antiangioedema (hereditary) agent¾Oxymetholone; Stanozolol 843, 844, 854.

Indications

Note: Bracketed information in the Indications section refers to uses that are not included in U.S. product labeling.

Accepted

Catabolic or tissue-depleting processes 811 (treatment)¾[Nandrolone decanoate, stanozolol], and oxandrolone 812 are indicated in conditions such as chronic infections, extensive surgery, [corticosteroid-induced myopathy, decubitus ulcers, burns] , or severe trauma, which require reversal of catabolic processes or protein-sparing effects. These agents are adjuncts to, and not replacements for, conventional treatment of these disorders.

Anemia (treatment)¾Nandrolone decanoate * is indicated for the treatment of anemia associated with renal insufficiency [and as adjuvant therapy for aplastic and sickle cell anemias]. Adequate iron intake is necessary for maximum therapeutic response.

[Nandrolone phenpropionate is indicated in the treatment of refractory deficient red cell production anemias. These may include aplastic anemia, myelofibrosis, myelosclerosis, agnogenic myeloid metaplasia, and hypoplastic anemias caused by malignancy or myelotoxic drugs. Anabolic steroid therapy should not replace other supportive measures.]

Oxymetholone is indicated in the treatment of bone marrow failure anemias and deficient red cell production anemias. Acquired and congenital aplastic anemias, myelofibrosis, and hypoplastic anemias due to myelotoxic medication often respond to oxymetholone. Oxymetholone should not replace other supportive measures such as transfusions; correction of iron, folic acid, vitamin B 12, or pyridoxine deficiency; antibacterial therapy; or the use of corticosteroids. 3

[Stanozolol is effective in raising hemoglobin concentrations in some cases of aplastic anemia (congenital or idiopathic).]

Carcinoma, breast (treatment)¾Anabolic steroids such as [nandrolone decanoate] * and nandrolone phenpropionate are indicated as treatment for palliation of inoperable metastatic breast cancer in postmenopausal women. However, anabolic steroids should be considered for use only after inadequate response to newer, less toxic medications such as tamoxifen in hormonally responsive breast cancer. 862 Anabolic steroids have also been used to treat breast cancer in premenopausal women who have undergone oophorectomy and are considered to have a hormone-responsive tumor. 816, 823, 830, 842, 848

Angioedema, hereditary (prophylaxis)¾Stanozolol and oxymetholone * are indicated in the prophylaxis of hereditary angioedema to decrease the frequency and severity of attacks. 814

Angioedema, hereditary (treatment)¾[Stanozolol] and oxymetholone * are used in the treatment of hereditary angioedema. 801, 802

[Antithrombin III deficiency (treatment)] or

[Fibrinogen excess (treatment)]¾Stanozolol is indicated in the treatment of conditions associated with decreased fibrinolytic activity due to antithrombin III deficiency or excess fibrinogen. These conditions may include cutaneous vasculitis, scleroderma of Raynaud's disease, vasculitis of Behcet's disease, and complications of deep vein thrombosis such as venous lipodermatosclerosis. Stanozolol is indicated in the prevention of recurrent venous thrombosis associated with antithrombin III deficiency. Stanozolol may be of benefit in patients susceptible to or with a history of thromboembolism for the treatment of vascular disorders associated with these forms of reduced fibrinolytic activity.

[Growth failure (treatment adjunct)]¾Anabolic steroids may be used in children as an adjunct in the treatment of growth failure caused by pituitary growth hormone (GH) deficiency (pituitary dwarfism) or if the response to human growth hormone administration is inadequate.

[Turner's syndrome (treatment)]¾Oxandrolone is used in the treatment of the short stature that accompanies Turner's syndrome (gonadal dysgenesis in females). Although the therapy is controversial,

recent experimental reports seem to indicate that oxandrolone may be as effective as growth hormone and that oxandrolone may increase the efficacy of growth hormone therapy. 801, 804, 820, 821, 822, 824, 825, 826, 827, 828, 829

Unaccepted

Anabolic steroids have been used for the treatment of symptoms associated with osteoporosis. 812, 823, 831, 832, 849, 850, 861 However, this use has largely been discontinued because the questionable efficacy of these agents for this indication does not justify the risk of serious adverse effects. 850, 861

Oxandrolone and oxymetholone have been used for the treatment of alcoholic hepatitis with encephalopathy. 861 However, there is currently insufficient evidence to establish the efficacy of these agents for this indication. 861

Use of anabolic steroids by athletes is not recommended. 834 Objective evidence is conflicting and inconclusive as to whether these medications significantly increase athletic performance by increasing muscle strength. Weight gains reported by athletes are due in part to fluid retention, which is a potentially hazardous side effect of anabolic steroid therapy. The risk of other unwanted effects, such as testicular atrophy and suppression of spermatogenesis in males; menstrual disturbances and virilization, such as deepening of voice, development of acne, and unnatural growth of body hair in females; peliosis hepatis or other hepatotoxicity; and hepatic cancer outweigh any possible benefit received from anabolic steroids and make their use in athletes inappropriate.

* Not included in Canadian product labeling.

Pharmacology/Pharmacokinetics

Physicochemical characteristics:

Chemical group¾Anabolic steroids are synthetic derivatives of testosterone, and as such have androgenic properties. The deletion of the CH 3 group from the C-19 position results in reduction of its androgenic properties and retention of its anabolic, tissue-building properties. 853, 861 Since complete dissociation of anabolic and androgenic effects is not possible, many of the actions of anabolic steroids are similar to those of androgens.

The 17-alpha alkylated (oral methylated) anabolic steroids are oxandrolone, oxymetholone, and stanozolol. 859

Molecular weight¾Nandrolone decanoate: 428.66 8

Nandrolone phenpropionate: 406.57 8

Oxandrolone: 306.45 8

Oxymetholone: 332.49 8

Stanozolol: 328.50 8

Mechanism of action/Effect:

Anabolic steroid¾ Reverses catabolic processes and negative nitrogen balance by promoting protein anabolism and stimulating appetite if there is concurrently a proper intake of calories and proteins. 829, 841, 853

Antianemic¾ Anemias due to bone marrow failure: Increases production and urinary excretion of erythropoietin. 3

Anemias due to deficient red cell production: Stimulates erythropoietin production and may have a direct action on bone marrow. 3, 853, 861, 862

Anemias associated with renal disease: Increases hemoglobin and red blood cell volume.

Angioedema (hereditary) prophylactic¾ Increases serum concentration of C1 esterase inhibitor and, as a result, C2 and C4 concentrations. 834, 843, 844, 845

Half-life:

Oxandrolone¾ Biphasic:
1st phase¾0.55 hours.
2nd phase¾9 hours.

Time to peak serum concentration

Nandrolone decanoate intramuscular¾100-mg dose: 3 to 6 days.

Nandrolone phenpropionate intramuscular¾100-mg dose: 1 to 2 days.

Elimination:

Oxandrolone¾Renal; small amount fecal.

Precautions to Consider

Carcinogenicity

Hepatocellular carcinoma has been associated rarely with long-term, high-dose anabolic steroid therapy. 801, 3

Tumorigenicity

Hepatic neoplasms have been associated rarely with long-term, high-dose anabolic steroid therapy. 801

Mutagenicity

For oxandrolone¾Animal or in vitro mutagenicity studies have not been done. 812

For oxymetholone¾Studies have not been done. 3

For stanozolol¾Animal studies have not been done. 814

Pregnancy/Reproduction

Pregnancy¾Anabolic steroids are not recommended for use during pregnancy, since studies in animals have shown that anabolic steroids cause masculinization of the fetus. Risk-benefit must be carefully considered.

For oxandrolone: 812 Animal studies have also shown oxandrolone to cause embryotoxicity, fetotoxicity, and infertility, in addition to masculinization in offspring of animals receiving 9 times the human dose.

FDA Pregnancy Category X. 3

Breast-feeding

It is not known whether anabolic steroids are distributed into breast milk. 3, 812, 814 Problems in humans have not been documented. However, anabolic steroids are rarely used by lactating women. 851, 861

Pediatrics

Anabolic steroids should be used with caution in children and adolescents 3, 835 because of possible premature epiphyseal closure, 3 precocious sexual development in males, and virilization in females. The epiphyseal maturation may be accelerated more rapidly than linear growth in children, and the effect may continue for 6 months after the medication has been discontinued.

For stanozolol¾The safety and efficacy of stanozolol in children with hereditary angioedema have not been established. Attacks of hereditary angioedema may include symptoms such as life-threatening upper respiratory obstruction with or without severe gastrointestinal colic, 834, 845 but are generally infrequent in childhood. The risks from stanozolol therapy are substantially increased with long-term use. Therefore, long-term administration of stanozolol is generally not recommended in children, and should not be undertaken without consideration of risk-benefit involved and close follow-up for endocrine effects. 852

Geriatrics

Treatment of geriatric male patients with anabolic steroids may cause increased risk of prostatic hyperplasia or prostatic carcinoma. 3

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)¾not necessarily inclusive (>> = major clinical significance):

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

>> Anticoagulants, coumarin- or indandione-derivative or

Anti-inflammatory analgesics, nonsteroidal or 858, 861

Salicylates, in therapeutic doses 858, 861

(anticoagulant effect may be increased during concurrent use with anabolic steroids, especially 17-alpha-alkylated compounds, because of decreased procoagulant factor concentration 3 caused by alteration of procoagulant factor synthesis or catabolism and increased receptor affinity for the anticoagulant; anticoagulant dosage adjustment based on prothrombin time determinations may be required during and following concurrent use)

Antidiabetic agents, sulfonylurea 3 or

Insulin 3

(anabolic steroids may decrease blood glucose concentration; diabetic patients should be closely monitored for signs of hypoglycemia and dosage of hypoglycemic agent adjusted if necessary)

Corticosteroids, glucocorticoid, especially with significant mineralocorticoid activity or

Corticosteroids, mineralocorticoid or

Corticotropin, especially prolonged therapeutic use or

Sodium-containing medications or foods

(concurrent use with anabolic steroids may increase the possibility of edema; in addition, concurrent use of glucocorticoids or corticotropin with anabolic steroids may promote development of severe acne)

>> Hepatotoxic medications, other (see Appendix II)

(concurrent use with anabolic steroids may result in an increased incidence of hepatotoxicity; patients, especially those on prolonged administration or those with a history of liver disease, should be carefully monitored 815)

Somatrem or

Somatropin

(concurrent use of anabolic steroids with somatrem or somatropin may accelerate epiphyseal maturation)

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 diagnostic test results

Fasting blood sugar 3 and

Glucose tolerance test 3 and

Metyrapone test

(may be altered 3)

Thyroid function tests

(radioactive iodine uptake and thyroxine-binding capacity [TBC] may be decreased; the decreased concentrations of thyroxine-binding globulin result in decreased total T 3 and T 4 serum concentrations 3, 817, 818 and increased resin uptake of T 3 and T 4; 801, 3 altered tests usually persist for 2 to 3 weeks after stopping therapy 3, 823)

With physiology/laboratory test values

Alanine aminotransferase (ALT [SGPT]) and

Alkaline phosphatase 3 and

Aspartate aminotransferase (AST [SGOT]) 3 and

Creatine kinase (CK) 3

(values may be increased 3)

Bilirubin, serum 3 and

Calcium, chloride, inorganic phosphates, potassium, and sodium, serum 3

(concentrations may be increased 3)

Clotting factors II, V, VII, and X 3

(concentrations may be decreased 3)

Creatine and creatinine excretion 3

(may be increased; 3 effect usually lasts up to 2 weeks after therapy is discontinued)

Lipoproteins, high-density 3 and

Lipoproteins, low-density 3

(high-density lipoprotein concentration may be lowered; low-density lipoprotein concentration may be elevated 801, 3, 856, 857)

Prothrombin time 3

(may be increased 3)

Serum lipid, especially triglyceride, concentrations and

Urinary 17-ketosteroid (17-KS) excretion 3

(may be decreased 3)

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)¾ not necessarily inclusive (>> = major clinical significance).

Except under special circumstances, these medications should not be used when the following medical problems exist

>> Breast cancer, disseminated, in females with active hypercalcemia 3

>> Breast cancer in males 3

>> Hepatic function impairment, severe 3

>> Hypercalcemia, active or history of 861

(may be exacerbated or recurrence may result)

>> Nephrosis or nephrotic phase of nephritis 3

>> Prostate cancer 3

(tumor growth may be promoted)

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

Cardiac function impairment or

Hepatic function impairment or

Renal function impairment

(use of these medications may cause retention of sodium and water, resulting in edema, with or without congestive heart failure)

>> Coronary artery disease, history of or

>> Myocardial infarction, history of

(because of hypercholesterolemic effects of anabolic steroids)

Diabetes mellitus

(anabolic steroids may decrease blood sugar concentrations; insulin or oral hypoglycemic dosage may need to be adjusted)

Intolerance to anabolic steroids or androgens

Prostatic hyperplasia, benign

(further enlargement may occur)

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):

Calcium 3, 862

(measurement of serum concentrations recommended at regular intervals during anabolic steroid therapy in females with breast cancer 3)

>> Cholesterol 835, 849

(measurement of serum concentrations recommended at regular intervals during therapy because of possible decreased high-density lipoprotein and increased low-density lipoprotein, which may increase the risk of atherosclerosis 3)

Hematocrit value 3 and

Hemoglobin concentration 3

(recommended periodically to detect polycythemia in patients taking high doses of anabolic steroids 3)

>> Hepatic function determinations 3

(recommended at regular intervals during therapy because of possibility of hepatic dysfunction, peliosis hepatis, and liver cell tumors, especially with 17-alpha-alkylated compounds, which are more likely to cause hepatic dysfunction 3)

Iron concentrations, serum 3 and

Total iron-binding capacity (TIBC) determinations 3

(recommended at regular intervals during therapy because of possible iron deficiency anemia manifested by low serum iron and decrease in percentage of transferrin saturation)

X-ray studies 3

(recommended at 6-month intervals in children and adolescents 3, 835 to monitor bone age in order to prevent the risk of compromising adult height 3)

Side/Adverse Effects

Note: Peliosis hepatis and hepatic neoplasms, including hepatocellular carcinoma, have been associated with long-term, high-dose anabolic steroid therapy. These adverse reactions can be life-threatening or fatal. 3

The following side/adverse effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate)¾not necessarily inclusive:

Those indicating need for medical attention

Incidence more frequent

In females only

Virilism (acne or oily skin; enlarging clitoris; hoarseness or deepening of voice; menstrual irregularities; unnatural hair growth or loss) 3

Note: Enlarging clitoris, hoarseness or deepening of voice, and unnatural hair growth or loss usually are not reversible even after prompt discontinuance of therapy. The concurrent use of estrogens will not prevent virilization in females. 3

In prepubertal males only

Virilism (acne; enlarging penis; increased frequency of erections; unnatural hair growth)

In postpubertal males only

Bladder irritability 3 (frequent urge to urinate); breast soreness; gynecomastia 3, 848 (enlargement of breasts); priapism (frequent or continuing erections) 3

Incidence less frequent

In both females and males

Anemia, iron deficiency (loss of appetite; sore tongue); edema 3 (swelling of feet or lower legs; rapid weight gain); gastric irritation (nausea; vomiting) 3; hepatic dysfunction (yellow eyes or skin); leukemia 3 (bone pain); suppression of clotting factors (unusual bleeding)

In females only

Hypercalcemia (mental depression; nausea; vomiting; unusual tiredness)

In prepubertal males only

Unexplained darkening of skin

In geriatric males only

Prostatic carcinoma or prostatic hyperplasia 3 (difficult or frequent urination)

Incidence rare¾with prolonged therapy

In both females and males

Hepatic necrosis 3 (black, tarry stools; continuing feeling of discomfort; continuing headache; continuing unpleasant breath odor; vomiting of blood); hepatocellular carcinoma 3 (abdominal or stomach pain; unexplained weight loss); peliosis hepatis 3 (continuing loss of appetite; dark-colored urine; fever; hives; light-colored stools; nausea and vomiting; purple- or red-colored spots on body or inside the mouth or nose; sore throat)

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

Incidence more frequent

In males only

Acne

Incidence less frequent

In both females and males

Chills 3; decrease or increase in libido 3; diarrhea 3; feeling of abdominal or stomach fullness; muscle cramps; trouble in sleeping

In males only

Decreased sexual ability

Overdose

For more information on the management of overdose or unintentional ingestion, contact a Poison Control Center (see Poison Control Center Listing).

Clinical effects of overdose

The following effects have been selected on the basis of their potential clinical significance (possible signs and symptoms in parentheses where appropriate)¾not necessarily inclusive:Hepatotoxicity

Treatment of overdose

Treatment of overdose is symptomatic and supportive.

To decrease absorption¾In acute oral overdose, decontamination includes induced emesis and/or gastric lavage.

Monitoring¾Hepatic function.

Supportive care¾Patients in whom intentional overdose is confirmed or suspected should be referred for psychiatric consultation.

Patient Consultation

As an aid to patient consultation, refer to Advice for the Patient, Anabolic Steroids (Systemic).

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

Before using this medication

>> Conditions affecting use, especially:

Carcinogenicity¾Hepatocellular carcinoma associated with long-term, high-dose therapy

Tumorigenicity¾Hepatic neoplasms associated with long-term, high-dose therapy

Pregnancy¾Not recommended during pregnancy because of possible masculinization of fetus

Use in children¾Cautious use because of effects on growth and sexual development (precocious sexual development in males, virilization in females)

Use in the elderly¾Increased risk of prostatic hyperplasia or prostatic carcinoma

Other medications, especially anticoagulants (coumarin- or indandione-derivatives) or hepatotoxic medications

Other medical problems, especially breast cancer, coronary artery disease, hepatic function impairment, hypercalcemia, myocardial infarction, nephrosis, nephrotic phase of nephritis, or prostatic cancer

Proper use of this medication

>> Importance of not taking more medication than the amount prescribed; to do so may increase chance of side effects

>> Importance of diet high in proteins and calories while taking this medication to achieve maximum therapeutic effect

>> Proper dosing

Missed dose: If dosing schedule is¾Once daily: Taking as soon as possible; if not remembered until next day, not taking at all; not doubling doses
More than once daily: Taking as soon as possible; not taking if almost time for next dose; not doubling doses

>> Proper storage

Precautions while using this medication

Regular visits to physician to check progress during therapy

Diabetics: May decrease blood sugar concentrations

Side/adverse effects

Signs of potential side effects, especially

In females only¾Virilism or hypercalcemia

In prepubertal males only¾Virilism or unexplained darkening of skin

In postpubertal males only¾Bladder irritability, breast soreness, gynecomastia, or priapism

In geriatric males only¾Prostatic carcinoma or prostatic hyperplasia

In all patients, in addition to those side effects listed above¾Anemia, iron deficiency; edema; gastric irritation; hepatic dysfunction, necrosis, or carcinoma; leukemia; suppression of clotting factors; or peliosis hepatis

General Dosing Information

Many of the side/adverse effects of anabolic steroids are dose-related; therefore, patients should be placed on the lowest possible effective dose.

Diet/Nutrition

A well-balanced diet that provides adequate proteins and calories should accompany all anabolic steroid therapy to achieve a maximum therapeutic effect.

NANDROLONE

Summary of Differences

Category¾ Nandrolone decanoate¾Antianemic.
Nandrolone phenpropionate¾Antineoplastic.

Indications¾ Nandrolone decanoate is indicated in the treatment of anemia associated with renal insufficiency.
Nandrolone phenpropionate is indicated in the treatment of metastatic breast cancer in women.

Additional Dosing Information

See also General Dosing Information.

Nandrolone injections should be administered intramuscularly, preferably deep into the gluteal muscle.

When using nandrolone decanoate injection, an adequate iron intake is required for maximum response.

Parenteral Dosage Forms

NANDROLONE DECANOATE INJECTION USP

Usual adult and adolescent dose 835, 848

Females¾Intramuscular, 50 to 100 mg given at one- to four-week intervals.

Males¾Intramuscular, 50 to 200 mg given at one- to four-week intervals.

Note: When given at three- to four-week intervals, therapy may be continued for up to 12 weeks. If necessary, cycle may be repeated if second course is preceded by a four-week rest period.

In the treatment of severe disease states, such as metastatic breast cancer and refractory anemias, a higher dose, based on therapeutic response and the benefit-to-risk ratio, may be required.

Usual pediatric dose

Children up to 2 years of age¾Dosage has not been established.

Children 2 to 13 years of age¾Intramuscular, 25 to 50 mg every three to four weeks.

Children 14 years of age and over¾See Usual adult and adolescent dose. 835, 848, 855

Strength(s) usually available

U.S.¾50 mg per mL (Rx)[Deca-Durabolin] [Hybolin Decanoate] [Kabolin] [Generic]

100 mg per mL (Rx)[Deca-Durabolin] [Hybolin Decanoate] [Generic]

200 mg per mL (Rx)[Deca-Durabolin] [Generic]

Canada¾50 mg per mL (Rx)[Deca-Durabolin (benzyl alcohol 10%) (sesame oil)]

100 mg per mL (Rx)[Deca-Durabolin (benzyl alcohol 10%) (sesame oil)]

Packaging and storage:

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

NANDROLONE PHENPROPIONATE INJECTION USP

Usual adult dose

Intramuscular, 25 to 100 mg per week.

Note: Therapy may be continued for up to 12 weeks. If necessary, cycle may be repeated if second course is preceded by a four-week rest period.

Usual pediatric dose

Dosage has not been established.

Strength(s) usually available

U.S.¾25 mg per mL (Rx)[Durabolin] [Generic]

50 mg per mL (Rx)[Durabolin-50] [Hybolin-Improved] [Generic]

Canada¾Not commercially available. 806

Packaging and storage:

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

OXANDROLONE

Summary of Differences

Indications: Indicated in the treatment of catabolic or tissue-depleting processes.

Additional Dosing Information

See also General Dosing Information.

In adults, 2 to 4 weeks of therapy are usually adequate. In both adults and children, therapy may be repeated intermittently as needed.

Oral Dosage Forms

Note: Bracketed uses in the Dosage Forms section refer to categories of use and/or indications that are not included in U.S. product labeling.

OXANDROLONE TABLETS USP

Usual adult and adolescent dose

Oral, 2.5 mg two to four times a day. 835

Note: The dosage may range from 2.5 to 20 mg per day.

Usual pediatric dose

Children¾Oral, 250 mcg (0.25 mg) per kg of body weight per day.

[Turner's syndrome]¾Oral, 50 mcg to 125 mcg (0.05 to 0.125 mg) per kg of body weight per day. 820, 828, 836, 837, 838, 839 Generally, the patient should be started and maintained on the lowest effective dose to minimize the potential for adverse effects. 820, 846

Strength(s) usually available

U.S.¾2.5 mg (Rx)[Oxandrin (scored) (lactose) 863]

Canada¾Not commercially available.

Packaging and storage:

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

OXYMETHOLONE

Summary of Differences

Category: Antianemic; angioedema (hereditary) agent.

Indications: Indicated in treatment of bone marrow failure anemias and in deficient red cell production anemias; also used in prophylaxis and treatment of hereditary angioedema.

Additional Dosing Information

See also General Dosing Information.

Oxymetholone should be used for a minimum of 3 to 6 months, since a response is not always immediately observed. 3

Following remission of the anemia, some patients may be maintained without oxymetholone while others may be maintained on a low daily dose. Patients with congenital aplastic anemia usually require continued therapy with an appropriate maintenance dose. 3

Oral Dosage Forms

OXYMETHOLONE TABLETS USP

Usual adult and adolescent dose

Oral, 1 to 5 mg per kg of body weight per day. 3, 848

Note: The usual effective dose is 1 to 2 mg per kg of body weight a day, but higher doses may be required in some patients. 3 Treatment of refractory anemias may require 3 to 6 months.

Usual pediatric dose

Premature infants and neonates¾Oral, 175 mcg (0.175 mg) per kg of body weight or 5 mg per square meter of body surface area per day as a single dose. 847

Infants and children¾See Usual adult and adolescent dose.
3

Strength(s) usually available

U.S.¾50 mg (Rx)[Anadrol-50 (scored) 3]

Canada¾50 mg (Rx)[Anapolon 50 (scored) (lactose)]

Packaging and storage:

Store below 40 °C (104 °F), preferably between 15 and 30 °C (59 and 86 °F), 3 unless otherwise specified by the manufacturer. Store in a well-closed container. 7

STANOZOLOL

Summary of Differences

Category: Angioedema (hereditary) prophylactic.

Indications: Stanozolol is indicated in the prophylaxis of hereditary angioedema to decrease the frequency and severity of attacks and used in treatment of hereditary angioedema.

Oral Dosage Forms

STANOZOLOL TABLETS USP

Usual adult and adolescent dose

Oral, 2 mg three times a day to 4 mg four times a day for 5 days, initially. 801, 835

Note: A dose of 2 mg two times a day may be used in young women, who are particularly susceptible to the androgenic effects of stanozolol.

The dosage for continuous treatment of hereditary angioedema should be individualized according to patient response. After a favorable response is obtained, the dose should be decreased at intervals of 1 to 3 months to a maintenance dose of 2 mg a day; some patients may respond to a maintenance dose of 2 mg every other day. During the dose-reduction phase, close monitoring of patient response is indicated, especially if the patient has a history of upper respiratory tract involvement.

Usual pediatric dose

Children up to 6 years of age¾Oral, 1 mg a day, to be administered only during an attack. 801

Children 6 to 12 years of age¾Oral, up to 2 mg a day, to be administered only during an attack. 801

Strength(s) usually available

U.S.¾2 mg (Rx)[Winstrol (scored) (lactose)]

Canada¾Not commercially available.

Packaging and storage:

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