NEOMYCIN (Oral-Local)

Category

Hepatic encephalopathy therapy adjunct; bowel preparation (preoperative) adjunct.

Indications

Accepted

Bowel preparation, preoperative¾Oral-local neomycin is indicated concurrently with enteric-coated erythromycin base as part of an adjunctive regimen for the suppression of normal bacterial flora in the preoperative preparation of the bowel. 8, 14

Hepatic encephalopathy (treatment adjunct)¾Oral-local neomycin is indicated in the adjunctive treatment of hepatic encephalopathy. 14

Not all species or strains of a particular organism may be susceptible to neomycin.

Unaccepted

Oral neomycin is not indicated in the treatment of systemic infections because it is poorly absorbed. It is not effective against Pseudomonas aeruginosa .
Oral neomycin has been used in the treatment of hyperlipidemia; however, its use is not recommended because other available medications have a more favorable risk/benefit ratio. 30

Pharmacology

Mechanism of action/Effect:

Antibacterial (oral-local)¾Aminoglycoside; actively transported across the bacterial cell membrane, binds to a specific receptor protein on the 30 S subunit of bacterial ribosomes, and interferes with an initiation complex between mRNA (messenger RNA) and the 30 S subunit, inhibiting protein synthesis. RNA may be misread, thus producing nonfunctional proteins; polyribosomes are split apart and are unable to synthesize protein.
Oral nonabsorbable antibiotics suppress the growth of bacteria in the bowel. Oral neomycin is thought to reduce the production of ammonia in the intestine by inhibiting urease-producing bacteria responsible for catalyzing ammonia synthesis. 26

Precautions to Consider

Cross-sensitivity and/or related problems

Patients hypersensitive to one aminoglycoside may be hypersensitive to other aminoglycosides also. 14

Carcinogenicity/Mutagenicity

Long-term studies in animals have not been done to evaluate the carcinogenic or mutagenic potential of oral neomycin. 8, 14

Pregnancy/Reproduction

Fertility¾Long-term studies in animals have not been done to evaluate the effect of oral neomycin on fertility. 8, 14

Pregnancy¾Neomycin crosses the placenta and may be nephrotoxic in the human fetus. In addition, some aminoglycosides (e.g., streptomycin, tobramycin) have been reported to cause total irreversible, bilateral congenital deafness in children whose mothers received aminoglycosides during pregnancy. 8, 14

FDA Pregnancy Category D.

Breast-feeding

It is not known whether neomycin, taken orally, is excreted in breast milk. However, aminoglycosides are poorly absorbed from the gastrointestinal tract, and problems in humans have not been documented. 8

Pediatrics

Acute aminoglycoside-induced toxicity is more likely to occur in premature infants and neonates. 8, 14

Geriatrics

Since geriatric patients may be at greater risk of aminoglycoside-induced toxicity because of an age-related decrease in renal function, monitoring of renal function during therapy with aminoglycosides is recommended in these patients. Recommended doses should not be exceeded.

Dental

Oral-local neomycin may cause irritation or soreness of the mouth. 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.
Aminoglycosides, other or

Capreomycin 24, 28

(if significant systemic absorption of oral neomycin occurs, concurrent systemic use of these medications, especially in patients with renal insufficiency, may increase the potential for ototoxicity, nephrotoxicity, and neuromuscular blockade; hearing loss may occur and may progress to deafness even after discontinuation of the drug and is usually permanent; neuromuscular blockade may result in skeletal muscle weakness and respiratory depression or paralysis; treatment with anticholinesterase agents or calcium salts may help reverse the blockade)

Anesthetics, halogenated hydrocarbon inhalation or

Citrate-anticoagulated blood, massive transfusions or

Neuromuscular blocking agents 24, 28, 29

(if significant systemic absorption of oral neomycin occurs, concurrent use of these medications, especially in patients with renal insufficiency, may enhance neuromuscular blockade, resulting in skeletal muscle weakness and respiratory depression or paralysis; treatment with anticholinesterase agents or calcium salts may help reverse the blockade)

Chenodiol 25

(effectiveness of chenodiol may be decreased when used concurrently with antihyperlipidemics since they tend to increase cholesterol saturation of bile)

Digitalis glycosides, oral or 24, 28, 29, 31, 32, 33

Fluorouracil (5-FU) or 24

Methotrexate, oral or 24, 28, 29

Penicillin V or 24

Vitamin A, oral or 28, 29

Vitamin B 12, oral 24

(oral neomycin may impair absorption of these medications, resulting in decreased therapeutic effect; serum digoxin concentrations should be monitored and patients should be watched closely for evidence of altered digitalis effect)
(requirements for vitamin B 12, especially when used in combination with colchicine, and vitamin A may be increased in patients receiving oral neomycin concurrently)
(although no cases of clinical toxicity have been reported, concurrent use of oral antibiotics may increase serum digoxin concentrations in some individuals; in these individuals, alteration of the gut flora by antibiotics may diminish digoxin conversion to inactive metabolites, resulting in increased serum digoxin concentrations; although limited data are available, this interaction has been reported with oral use of erythromycins, neomycin, and tetracyclines)

Nephrotoxic medications, other (see Appendix II) or

Ototoxic medications, other (see Appendix II) 24, 29

(if significant systemic absorption of oral neomycin occurs, concurrent systemic use of these medications, especially in patients with renal insufficiency, may increase the potential for ototoxicity and nephrotoxicity; hearing loss may occur and may progress to deafness even after discontinuation of the drug and may be permanent)

Polymyxins, parenteral 24, 28, 29

(if significant systemic absorption of oral neomycin occurs, concurrent systemic use of these medications, especially in patients with renal insufficiency, may increase the potential for nephrotoxicity and neuromuscular blockade; neuromuscular blockade may result in skeletal muscle weakness and respiratory depression or paralysis; treatment with anticholinesterase agents or calcium salts may help reverse the blockade)

Warfarin 24, 27, 28, 29

(oral neomycin may enhance the effect of warfarin by altering vitamin K gut flora production, thereby decreasing vitamin K availability; it is not thought to have an effect on blood levels of prothrombin)

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, this medication should not be used when the following medical problems exist

>> Hypersensitivity to aminoglycosides

>> Intestinal obstruction

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

>> Eighth-cranial-nerve impairment

(if significant systemic absorption of oral neomycin occurs, it may cause auditory and vestibular toxicity 14)

>> Myasthenia gravis or

>> Parkinson's disease

(if significant systemic absorption of oral neomycin occurs, it may cause neuromuscular blockade, resulting in further skeletal muscle weakness 14)

>> Renal function impairment

(patients with impaired renal function may require a reduction in dose or discontinuation of oral neomycin 14)

>> Ulcerative lesions of the bowel

(significant amounts of oral neomycin may be absorbed through ulcerated or denuded mucosa of the bowel or if inflammation is present 14)

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):
Audiograms and 14

Renal function determinations 14

(may be required prior to and during treatment in patients with preexisting renal or eighth-cranial-nerve impairment or on long-term therapy; patients with impaired renal or eighth-cranial-nerve function may require a reduction in dose)

Side/Adverse Effects

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 rare 14

Malabsorption syndrome diarrhea); increased amount of gas); light-colored, frothy, fatty-appearing stools); nephrotoxicity greatly decreased frequency of urination or amount of urine); increased thirst); neuromuscular blockade difficulty in breathing); drowsiness); weakness); ototoxicity¾auditory (any loss of hearing, ringing or buzzing or a feeling of fullness in the ears); ototoxicity¾vestibular (clumsiness, dizziness, unsteadiness); skin rash
Those indicating need for medical attention only if they continue or are bothersome

Incidence more frequent 14

Gastrointestinal disturbance (diarrhea; nausea; vomiting); irritation or soreness of the mouth or rectal area

Overdose

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

Treatment of overdose

Recommended treatment consists of the following: 14

To decrease absorption¾Administering activated charcoal.
Specific treatment¾Hemodialysis to remove absorbed neomycin from the blood in severe cases. 8

Supportive care¾Maintaining urine output. Patients in whom intentional overdose is known or suspected should be referred for psychiatric consultation.

Patient Consultation

As an aid to patient consultation, refer to Advice for the Patient, Neomycin (Oral).
In providing consultation, consider emphasizing the following selected information (>> = major clinical significance):
Before using this medication

>> Conditions affecting use, especially:

Hypersensitivity to aminoglycosides
Pregnancy¾Neomycin crosses the placenta and may be nephrotoxic to the fetus
Use in children¾Aminoglycoside-induced toxicity is more likely to occur in premature infants and neonates
Use in the elderly¾Geriatric patients are at greater risk of aminoglycoside-induced toxicity
Dental¾Neomycin may cause irritation or soreness of the mouth
Other medical problems, especially eighth-cranial-nerve impairment, intestinal obstruction, myasthenia gravis, Parkinson's disease, renal function impairment, or ulcerative lesions of the bowel
Proper use of this medication

Taking on a full or empty stomach

Proper administration technique for oral solution

>> Compliance with full course of therapy

>> Proper dosing
Missed dose: Taking as soon as possible; not taking if almost time for next dose; not doubling doses
>> Proper storage
Side/adverse effects

Side effects are more likely to occur in elderly patients and in premature and newborn infants

Signs of potential side effects, especially malabsorption syndrome, nephrotoxicity, neuromuscular blockage, auditory ototoxicity, vestibular ototoxicity, and skin rash

General Dosing Information

Neomycin may be taken on a full or empty stomach.
Chronic hepatic insufficiency (hepatic encephalopathy) may require 2 to 4 grams daily for an extended period. Risks for the development of neomycin-induced toxicity progressively increase when treatment is prolonged for longer than 3 weeks. 8

If patients are unable to take neomycin orally in the treatment of hepatic encephalopathy, a 1% solution prepared from sterile neomycin sulfate powder may be administered as a retention enema.

Oral Dosage Forms

NEOMYCIN SULFATE ORAL SOLUTION USP

Usual adult and adolescent dose

Hepatic encephalopathy therapy adjunct¾
Oral, 1 to 3 grams every six hours for five or six days. 19, 21, 22, 23

Bowel preparation (preoperative) adjunct¾
Oral, 1 gram every hour for four hours, then 1 gram every four hours for the balance of twenty-four hours; or 1 gram at nineteen hours, eighteen hours, and nine hours before the start of surgery. 19, 21, 22, 23

Usual adult prescribing limits

Hepatic encephalopathy therapy adjunct¾
Up to 12 grams daily. 24, 26

Usual pediatric dose

Hepatic encephalopathy therapy adjunct¾
Oral, 625 mg to 1.75 grams per square meter of body surface every six hours for five or six days. 20

Bowel preparation (preoperative) adjunct¾
Oral, 14.7 mg per kg of body weight or 417 mg per square meter of body surface every four hours for three days. 20

Strength(s) usually available

U.S.¾125 mg per 5 mL (Rx)[Mycifradin (methylparaben) (propylparaben)] [Generic]

Canada¾125 mg per 5 mL (Rx)[Mycifradin (methylparaben) (propylparaben)]

Packaging and storage:

Store preferably between 15 and 30 °C (59 and 86 °F), unless otherwise specified by manufacturer. Store in a tight, light-resistant container. Protect from freezing.

Auxiliary labeling:

· Continue medicine for full time of treatment.

Note: When dispensing, include a calibrated liquid-measuring device.

NEOMYCIN SULFATE TABLETS USP

Usual adult and adolescent dose

See Neomycin Sulfate Oral Solution USP.

19, 21, 22, 23

Usual adult prescribing limits

See Neomycin Sulfate Oral Solution USP .

Usual pediatric dose

See Neomycin Sulfate Oral Solution USP.

20

Strength(s) usually available

U.S.¾500 mg (Rx) [Generic]

Canada¾500 mg (Rx)[Mycifradin]

Packaging and storage:

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

Stability:

Tablets may vary in color; this variation does not affect their potency.

Auxiliary labeling:

· Continue medicine for full time of treatment.

Note: Dispense in a glass bottle, unless otherwise specified by manufacturer.

References

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