Neosulf

Neomycin sulfate

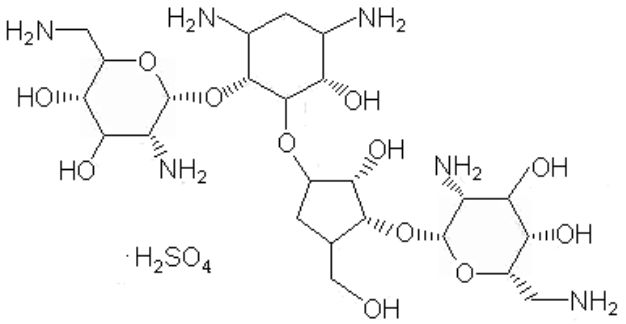
PRODUCT INFORMATION

Name of the Medicine

The active ingredient of Neosulf is Neomycin sulfate.

The chemical name for Neomycin sulfate is (1S-(1a,4a,5b,5a))-1,5,6-Trideoxy-4-O-beta-D-glucopyranosyl-5-(hydroxymethyl)-1-((4,5,6-trihydroxy-3-(hydroxymethyl)-2-cyclohexen-1-yl)amino)-D-chiro-inositol.

Its structural formula is:



Molecular formula:	Molecular weight:	CAS Registry No.:
$C_{23}H_{46}N_6O_{13}.3H_2SO_4$	908.87	1405-10-3

Description

Each tablet contains 500 mg of neomycin sulfate. The tablets also contain inactives including lactose.

Pharmacology

Neomycin is an aminoglycoside antibiotic which is usually bactericidal in action. Although the exact mechanism of action has not been fully established, the drug appears to inhibit protein synthesis in susceptible bacteria by irreversibly binding to 30S ribosomal subunits.

In general, neomycin is active against many aerobic Gram-negative bacteria and some aerobic Gram-positive bacteria. It is inactive against viruses, fungi and most anaerobic bacteria.

Indications

Bowel sterilisation before surgery.

Contraindications

Neomycin is contraindicated in the presence of intestinal obstruction, and in patients with a history of hypersensitivity to the drug.

Neomycin is also contraindicated in patients with inflammatory or ulcerative gastrointestinal disease because of the potential for enhanced gastrointestinal absorption of neomycin.

Precautions

Systemic absorption of neomycin occurs following oral administration, and toxic reactions may occur.

Neurotoxicity (including ototoxicity) and nephrotoxicity following the oral use of neomycin have been reported, even when used in recommended doses. Higher doses of neomycin and/or administration for longer periods than are recommended have a potential for producing ototoxicity and nephrotoxicity, even in patients with normal renal function. The risk of hearing loss continues after drug withdrawal.

The risk of ototoxicity and nephrotoxicity is greater in patients with impaired renal function or impaired hearing. Use in such patients should be considered only when alternative therapy is clearly contraindicated.

Patients with renal insufficiency may develop toxic neomycin blood levels unless doses are properly regulated. If renal insufficiency develops during treatment, the dosage should be reduced or the antibiotic discontinued.

Neuromuscular blockade and respiratory paralysis have been reported following the oral use of neomycin.

As with other antibiotics, the use of neomycin may result in the overgrowth of nonsusceptible organisms, particularly fungi. If superinfection occurs during neomycin therapy, the drug should be discontinued and appropriate therapy instituted.

Cross sensitivity between aminoglycosides may occur.

Oral neomycin at high doses may produce a malabsorption syndrome for a variety of substances including fat, nitrogen, cholesterol, carotene, glucose, xylose, lactose, sodium, calcium, cyanocobalamin and iron.

Use in Pregnancy (Risk Category: D)

Aminoglycosides cross the placenta. There is evidence of selective uptake of aminoglycosides by the fetal kidney resulting in damage (probably reversible) to immature nephrons. Eighth cranial nerve damage has also been reported following in-utero exposure to some of the aminoglycosides. Because of their chemical similarity, all aminoglycosides must be considered potentially nephrotoxic and ototoxic to the fetus. It should also be noted that therapeutic blood concentrations in the mother do not equate with safety for the fetus.

Use in Lactation

Aminoglycosides are excreted in human milk. Therefore, administration to nursing mothers is not recommended unless the expected benefits to the mother clearly outweigh the potential risks to the infant.

Use in Children

The safety and efficacy of oral neomycin for pre-operative suppression of intestinal bacteria in patients less than 18 years of age have not been established. If treatment of a patient less than 18 years of age is necessary, neomycin should be used with caution.

Interactions with other medicines

Neomycin should not be given concurrently and/or sequentially with other systemic, oral or topical aminoglycoside antibiotics or other potentially nephrotoxic, neurotoxic or ototoxic drugs, as toxicity may be additive.

Concurrent administration of neomycin with a neuromuscular blocking agent may enhance neuromuscular blockade and lead to respiratory paralysis. The use of neomycin in patients receiving such agents should therefore be avoided.

The concurrent use of neomycin with potent diuretics such as ethacrynic acid or frusemide should be avoided, since certain diuretics themselves may cause ototoxicity. In addition, when administered intravenously, diuretics may enhance neomycin toxicity by altering the antibiotic concentration in serum and tissue.

Although the clinical significance has not been clearly established, neomycin has been reported to decrease the gastrointestinal absorption of penicillin V, oral vitamin B_{12}, methotrexate, 5-fluorouracil, and digoxin. Oral neomycin may enhance the effect of coumarin in anticoagulation by decreasing vitamin K availability.

Adverse Effects

The most common adverse effects reported with the use of oral neomycin sulfate are nausea, vomiting and diarrhoea.

Prolonged oral therapy may cause a malabsorption syndrome with steatorrhoea and diarrhoea which can be very severe.

Nephrotoxicity, ototoxicity and neuromuscular blockade have been reported.

Overdosage

In cases of overdosage, it is advisable to contact the Poisons Information Centre (131126) for recommendation on the management and treatment of overdosage.

Dosage and Administration

For pre-operative intestinal antisepsis, oral neomycin sulfate is usually given for 24 hours. The usual adult dosage is 2 tablets each hour for four hours, then 2 tablets every four hours until a total of 16 tablets have been administered.

Presentation and Storage Conditions

Neosulf Neomycin sulfate 500 mg tablet: white, scored; packed in bottles of 25.

Store below 25°C. Protect from light.

Poison Schedule of Medicine

S4 – Prescription Only Medicine

Name and Address of the Sponsor

Alphapharm Pty Limited
Chase Building 2
Wentworth Park Road
Glebe NSW 2037

ABN 93 002 359 739

www.alphapharm.com.au

Date of Approval

Approved by the Therapeutic Goods Administration on 15 February 1995.

Date of most recent amendment: 19 January 2007.