

Prescribing Information/Insert

NEOBACRIN ointment

A white ointment containing in each gram neomycin sulphate 5mg and zinc bacitracin 500 i.u.

EXCIPIENTS

Liquid paraffin, White soft paraffin

THERAPEUTIC INDICATIONS

Skin conditions: Impetigo, sycosis barbae, furunculosis, secondarily infected wounds, ulcers and localised burns, infected eczematoid and pyogenic dermatitis.

POSODOLOGY AND METHOD OF ADMINISTRATION

Apply two or three times a day.

Treatment should not be continued for more than seven days without medical supervision. Applications should not exceed 60g daily for 3 weeks, and thereafter not be repeated for at least 3 months.

Use in children:

Neobacrin Ointment is suitable for use in children (2 years and over) at the same dose as adults. A possibility of increased absorption exists in very young children, thus Neobacrin Ointment is not recommended for use in neonates and infants (<2 years) (See Contra-Indications and Special Warnings and Special Precautions for Use).

Use in the elderly

Neobacrin Ointment is suitable for use in the elderly. Caution should be exercised in cases where a decrease in renal function exists and significant systemic absorption of neomycin sulphate may occur. (See Special Warnings and Special Precautions for Use).

Dosage in renal impairment

Dosage should be reduced in patients with reduced renal function (see Special Warnings and Special Precautions for Use).

CONTRA-INDICATIONS

Hypersensitivity to any component of the preparation.

The treatment of otitis externa when the ear drum is perforated because of the risk of ototoxicity.

Due to the known ototoxic and nephrotoxic potential of neomycin sulphate, the use of Neobacrin in large quantities or on large areas for prolonged periods of time is not recommended in circumstances where significant systemic absorption may occur.

A possibility of increased absorption exists in very young children, thus Neobacrin is not recommended for use in neonates and infants (<2 years). In neonates and infants, absorption by immature skins may be enhanced and renal function may be immature.

SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE

Following significant systemic absorption, aminoglycosides such as neomycin can cause irreversible ototoxicity; and neomycin and bacitracin zinc have nephrotoxic potential.

In renal impairment the plasma clearance of neomycin is reduced (See Dosage in Renal Impairment).

Application of Neobacrin to chronic leg ulcers, hypostatic eczema, pemphigus and extensive burns should be avoided.

Prolonged and repeated application and use of occlusive dressings increases the possibility of hypersensitivity reactions.

There may be cross-antigenicity with other aminoglycoside antibiotics.

Prolonged application may result in overgrowth of non-susceptible organisms, eg. fungi.

Concurrent administration of other aminoglycosides is not recommended.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

Following significant systemic absorption, neomycin sulphate can intensify and prolong the respiratory depressant effects of neuromuscular blocking agents.

USE DURING PREGNANCY AND LACTATION

There is little information to demonstrate the possible effect of topically applied neomycin in pregnancy and lactation. However, neomycin present in maternal blood can cross the placenta and may give rise to a theoretical risk of foetal toxicity, thus use of Neobacrin is not recommended in pregnancy or lactation.

UNDESIRABLE EFFECTS

Severe local allergic reactions to bacitracin have been reported.

Neobacrin is usually well tolerated. However, if the skin lesion persists after 7-14 days of therapy, the possibility of cutaneous manifestation of underlying disease, local sensitization or bacterial resistance should be investigated.

OVERDOSE

Symptoms and signs:-

No specific symptoms or signs have been associated with excessive use of Neobacrin Ointment and Eye Ointment. However, consideration should be given to significant systemic absorption (See Special Warnings and Special Precautions for Use).

Management:-

Use of the product should be stopped and the patient's general status, hearing acuity, renal and neuromuscular functions should be monitored.

Blood levels of neomycin sulphate and bacitracin zinc should also be determined, and haemodialysis may reduce the serum level of neomycin sulphate.

SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C

SHELF-LIFE

30 months

NATURE AND CONTENTS OF CONTAINER

Squeezable aluminium tubes containing 20g ointment

MANUFACTURED BY:

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