SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

1.1 Brand Name : **Neoleb 1% Ointment**
1.2 Generic Name : **Neomycin Sulphate Ointment USP 1% w/w**
1.3 Strength : **Neomycin Sulphate 1.0% w/w**
1.4 Pharmaceutical Form : **Ointment**

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Neomycin Sulphate	BP	1.0 % w/w
Chlorocresol (as preservative)	BP	0.1 % w/w
Ointment base		q.s.

3. PHARMACEUTICAL FORM

Ointment
White coloured, perfumed translucent Ointment.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Neoleb Ointment is indicated for the treatment of bacterial skin infections.

4.2 Posology and method of administration

Before applying Neoleb Ointment (Neomycin Sulphate), wash the affected area with soap and water, and dry thoroughly.

Apply a generous amount of ointment to the affected area, and rub gently.

For Bacterial skin infections
To the skin
Adult & Children 2 years of age & older: Apply up to 3 times a day, for short-term use only.
For Child under 2years of age – ask your physician.

4.3 Contraindications

Neoleb Ointment is contraindicated in Neonates. Known hypersensitivity to Neomycin or any ingredient in the formulation. Neomycin Sulphate Ointment is contraindicated to apply on a child's diaper area, especially if the skin is raw, unless directed to do so by a physician.

4.4 Special warnings and special precautions for use

Large areas: If large areas of skin are being treated with Neomycin Sulphate ototoxicity may be a hazard, particularly in children and the elderly, and in those with renal impairment. Do not use Neomycin Sulfate Ointment in the eyes.

4.5 Interaction with other FPPs and Other forms of Interaction

Topical preparations of Neomycin Sulphate should not be used with Amikacin, Gentamicin, Kanamycin, Tobramycin in circumstances where significant absorption could occur for example application to burnt or broken skin, use of large quantities, or on large areas for prolonged periods. Using Succinylcholine together with Neomycin topical may increase the effects of Succinylcholine. Using Metocurine together with Neomycin topical may increase the effects of Metocurine. Using Vecuronium together with Neomycin topical may increase the effects of Vecuronium.

4.6 Pregnancy and lactation

Studies in pregnant women have demonstrated a risk to the fetus after topical application of Neomycin Sulphate Ointments. It should not be applied to the breast prior to breastfeeding.

4.7 Effects on ability to drive and use machines

Not Known

4.8 Undesirable effects

Neoleb Ointment (Neomycin Sulphate) may show sensitisation (cross sensitivity with other aminoglycosides may occur). Irritation, redness, itching, rash, sensitivity to light, blurred vision hearing difficulty. The above mentioned possible side effects may occur from Neomycin Sulphate Ointment. These side effects are possible, but do not always occur.

4.9 Overdose & Treatment

Not known

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group: Antibacterial.

ATC Code: D06AX04

Neomycin Sulphate belonging to aminoglycoside class of antibiotic which is having a concentration-dependent bactericidal activity by protein synthesis inhibition against most gram-negative aerobic and facultative anaerobic bacilli but not against gram-negative anaerobes and most gram-positive bacteria. In another words, Neomycin Sulphate may works by preventing the bacterial growth by stopping the production of essential protein in bacterial cells. They require only short contact time, and are most effective against susceptible bacterial populations that are rapidly multiplying.

5.2 Pharmacokinetic properties

Neomycin Sulphate after topical application may not absorbed to any appreciable extent from intact skin, it readily absorbed through denuded or abraded areas of skin or skin that has lost the keratin layer (i.e., wounds, burns, ulcers). Rapidly absorbed from the peritoneum, draining sinuses, wounds, or surgical sites. Plasma concentrations reach to higher level following topical application to open wounds, burns, or granulating surfaces.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

SN	Ingredients	Spec.
01.	Chlorocresol	BP
02.	Propylene Glycol	BP
03.	Cetomacrogol Emu. Wax	BP
04.	Liquid Paraffin (H)	BP
05.	White Soft Paraffin (White Petroleum Jelly)	BP
06.	Perfume Spring Awakening (P-4200)	IH

6.2 Incompatibilities

Not sufficient data available

6.3 Shelf life

24 month from the date of manufacturing.

6.4 Special precautions for storage

Do not Freeze. Store at a temperature not exceeding 30°C. Protect from light. Keep Out of reach of Children.

6.5 Nature and contents of container

15 g. in an aluminium lacquered collapsible tube in an inner carton.

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORISATION NUMBER

07977/08848/NMR/2021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Oct 22, 2022

10 DATE OF REVISION OF THE TEXT

01/01/2023