

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Naseptin Nasal Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine dihydrochloride 0.1% w/w

Neomycin sulfate 0.5% w/w

Excipients with known effect:

Contains 8% w/w (80mg/g) cetostearyl alcohol

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

A smooth white cream with a fatty odour.

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Eradication of nasal infection with, and carriage of, Staphylococci.

4.2. Posology and Method of Administration

For nasal application only.

A small amount of Naseptin is placed on the little finger and applied to the inside of each nostril.

For prophylaxis: Naseptin is applied as above, twice daily, to prevent patients from becoming carriers and to inhibit the dispersion of Staphylococci.

For eradication of infection: Naseptin is applied four times daily for 10 days to eliminate organisms from the nares.

Children and elderly patients: There are no special dosage recommendations for either children or elderly patients.

4.3 Contraindications

Patients who have previously shown a hypersensitivity reaction to neomycin or chlorhexidine, although such reactions are extremely rare.
Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

For nasal application only. Keep out of the eyes and ears.

Irritative skin reactions can occasionally occur. Prolonged use of neomycin can lead to skin sensitisation, ototoxicity and nephrotoxicity. Use with caution in children, elderly patients and patients with impaired hearing (see Section 4.8 'Undesirable effects').

This medicinal product contains cetostearyl alcohol which may cause local skin reactions (e.g., contact dermatitis).

4.5 Interaction with other Medicinal Products and other Forms of Interaction

None known.

4.6 Pregnancy and Lactation

Chlorhexidine and neomycin cannot be detected in the blood following application of Naseptin and its use is unlikely to have any effect on the foetus or on breast feeding.

4.7 Effects on Ability to Drive and Use Machines

None known.

4.8 Undesirable effects

Tabulated list of adverse reactions

Undesirable effects are listed by MedDRA System Organ Classes.

Assessment of undesirable effects is based on the following frequency groupings:

Very common: $\geq 1/10$

Common: $\geq 1/100$ to $< 1/10$

Uncommon: $\geq 1/1,000$ to $< 1/100$

Rare: $\geq 1/10,000$ to $< 1/1,000$

Very rare: $< 1/10,000$

Not known: cannot be estimated from the available data

System Organ Class	Frequency	Undesirable Effect
Immune system disorders	Not known	<ul style="list-style-type: none">• anaphylaxis
Nervous system disorders	Not known	<ul style="list-style-type: none">• temporary hyposmia• temporary ageusia
Ear and labyrinth disorders	Not known	<ul style="list-style-type: none">• ototoxicity¹
Skin and subcutaneous tissue disorders	Not known	<ul style="list-style-type: none">• Irritative skin reactions• skin sensitisation
Renal and urinary disorders	Not known	<ul style="list-style-type: none">• nephrotoxicity
General disorders and administration site conditions	Not known	<ul style="list-style-type: none">• application site discolouration

¹Use with caution in children, elderly patients and patients with impaired hearing (see Section 4.4 'Special warnings and precautions for use').

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9. Overdose

Accidental ingestion of the contents of a Naseptin tube is unlikely to have any adverse effects on the patient.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other antibiotics for topical use

ATC code: D06AX

Chlorhexidine is effective against a wide range of Gram negative and Gram positive vegetative bacteria, yeasts, dermatophyte fungi and lipophilic viruses. It is inactive against bacterial spores except at elevated temperatures.

Neomycin is a rapidly bactericidal aminoglycoside antibiotic effective against Gram positive organisms including staphylococci and a wide range of Gram negative organisms. Strains of *Pseudomonas aeruginosa* are resistant to neomycin, as are fungi and viruses.

5.2. Pharmacokinetic Properties

Because of its cationic nature, chlorhexidine binds strongly to the skin, mucosa and other tissues and is thus very poorly absorbed. No detectable blood levels have been found in man following oral use and percutaneous absorption, if it occurs at all, is insignificant.

Neomycin is either not absorbed or is absorbed only minimally through intact skin. Any neomycin which is absorbed will be rapidly excreted by the kidneys in an unchanged state.

5.3. Pre-clinical Safety Data

There are no pre-clinical data of relevance to the prescriber which are additional to those already included in other sections of the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Medium-chain triglycerides, cetostearyl alcohol, cetostearyl alcohol/ethylene oxide condensate, purified water.

6.2. Incompatibilities

Hypochlorite bleaches may cause brown stains to develop in fabrics which have previously been in contact with preparations containing chlorhexidine.

Chlorhexidine is incompatible with soap and other anionic agents.

6.3. Shelf-Life

3 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Collapsible, internally lacquered aluminium tubes of 15g with white food-grade polyethylene screw caps.

6.6. Instructions for Use, Handling and Disposal

For nasal application only.

7. MARKETING AUTHORISATION HOLDER

Alliance Pharmaceuticals Ltd
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Chippenham
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SN15 2BB

8. MARKETING AUTHORISATION NUMBER(S)

PL 16853/0024

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/01/2007

10 DATE OF REVISION OF THE TEXT

28/01/2026