

## **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: 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. Contra-Indications**

Patients who have previously shown a hypersensitivity reaction to neomycin or chlorhexidine, although such reactions are extremely rare.

#### **4.4. Special warnings and precautions for use**

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

Naseptin contains Arachis oil (peanut oil) and should not be taken/applied by patients known to be allergic to peanut. As there is a possible relationship between allergy to peanut and allergy to Soya, patients with Soya allergy should also avoid Naseptin.

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').

#### **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**

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"><li>• anaphylaxis</li></ul>
Nervous system disorders	Not known	<ul style="list-style-type: none"><li>• temporary hyposmia</li><li>• temporary ageusia</li></ul>
Ear and labyrinth disorders	Not known	<ul style="list-style-type: none"><li>• ototoxicity<sup>1</sup></li></ul>
Skin and subcutaneous tissue disorders	Not known	<ul style="list-style-type: none"><li>• Irritative skin reactions</li><li>• skin sensitisation</li></ul>
Renal and urinary disorders	Not known	<ul style="list-style-type: none"><li>• nephrotoxicity</li></ul>

<sup>1</sup>Use 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. Tel: Freephone 0800 100 3352. Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

## **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**

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**

Arachis oil, 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 30°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  
Wiltshire  
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**

25/05/2017