Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Naseptin 0.1% & 0.5% w/w Nasal Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Chlorhexidine Dihydrochloride	0.1	% w/w
Neomycin Sulfate	0.5	% w/w (3250 IU/g)

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

Nasal cream
White, non-greasy, water-miscible nasal cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

'Naseptin' is an antimicrobial cream intended for application to the nares. It is used for eradicating staphylococcal infections, and carriage in the nose.

4.2 Posology and method of administration

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.

4.3 Contraindications

Hypersensitivity to chlorhexidine and neomycin or to any of the excipients listed in section 6.1.

Some patients have 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.

Topical application of neomycin preparations can cause skin sensitisation in a small number of patients. Prolonged use of neomycin can lead to ototoxicity and nephrotoxicity (see Section 4.8 ‘Undesirable effects’).

If no improvement occurs or there is aggravation, stop use and consult the physician.

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

See Section 6.2.

4.6 Fertility, pregnancy and lactation

No special precautions are necessary.

4.7 Effects on ability to drive and use machines

No precautions are necessary.

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: ≥1/10
Common: ≥1/100 to <1/10
Uncommon: ≥1/1,000 to <1/100
Rare: ≥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	• anaphylaxis, hypersensitivity
Nervous system disorders	Not known	• temporary hyposmia • temporary ageusia
Ear and labyrinth disorders	Not known	• ototoxicity[1]
Skin and subcutaneous tissue disorders	Not known	• Irritative skin reactions • skin sensitisation
Renal and urinary disorders	Not known	• nephrotoxicity
General disorders and administration site conditions	Not known	• application site discolouration

[1]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 HPRA Pharmacovigilance. Website: www.hpra.ie

4.9 Overdose

Accidental ingestion
Accidental ingestion of the contents of a Naseptin tube is not likely to have any adverse effect 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 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 Preclinical safety data

Chlorhexidine and neomycin are drugs on which extensive clinical experience has been obtained. Relevant information for the prescriber is provided elsewhere in the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl alcohol
Medium – Chain triglycerides
Cetostearyl alcohol/ethylene oxide condensate
Purified water

6.2 Incompatibilities

Chlorhexidine is incompatible with soap and other anionic agents.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 30˚C. Keep the tube tightly closed. Keep the tube in the outer carton.

6.5 Nature and contents of container

Internally lacquered aluminium tube (15g).

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Alliance Pharma (Ireland) Limited
United Drug Distributors, United Drug House
Magna Business Park, Magna Drive
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Dublin 24
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8 MARKETING AUTHORISATION NUMBER

PA2325/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983
Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

January 2023