

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Silcock’s Base Cream
White Soft Paraffin 20% w/w, Emulsifying Wax 15% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Emulsifying Wax	15.0	% w/w
Cetostearyl alcohol		
Sodium laurilsulfate		
Purified water		
White Soft Paraffin	20.0	% w/w

Excipients: also contains methyl parahydroxybenzoate (E218), ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cream
Smooth white homogenous cream with a faint characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

- a. Silcock's Base is a high lipid cream containing 20% w/w White Soft Paraffin which helps retain moisture in the skin by reducing the rate of normal evaporation.
- b. As an ointment base, soap substitute, and as a moisturiser and emollient in conditions such as chronic dermatosis, lichenification, etc.

4.2 Posology and method of administration

Apply as often as required to prevent itching and flaking dry skin.

Adults: as above
Babies: as above
Elderly: as above

4.3 Contraindications

Not to be used by persons known to be sensitive to the ingredients.

4.4 Special warnings and precautions for use

For external use only.
If there is no improvement or aggravation of the condition occurs consult your doctor.

Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

Sodium laurilsulfate (E 487) may cause local skin reactions (such as stinging or burning sensation) or increase skin reactions caused by other products when applied on the same area.

Sensitivity to SLS can vary according to body site, age and patient population (children, hydration level, skin color and disease). Patient populations with decreased skin barrier functions such as in atopic dermatitis are more sensitive to the irritant properties of SLS.

Parahydroxybenzoates may cause allergic reactions (possibly delayed).

Healthcare professionals should be aware that if this product comes into contact with dressings, clothing and bedding, the fabric can be easily ignited with a naked flame. Patients should be warned of this risk and advised to keep away from fire when using this product

This preparation may make skin and surfaces slippery – particular care is needed when bathing.

Silcock's Base should not be used to dilute steroid creams or ointments.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Fertility, pregnancy and lactation

- a) No animal reproduction/fertility study was carried out
- b) No study carried out
- c) No known reason for not using in fertile, pregnant or lactating women.

4.7 Effects on ability to drive and use machines

- 1) Presumed to be safe and unlikely to produce an effect.
- 2) Not applicable.
- 3) Not applicable.

4.8 Undesirable effects

Allergic reaction to parabens, which is rarely experienced.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code D02AC Soft paraffin and fat products

Emollient

The fats and oils in Silcock's Base form a layer on the skin to help prevent moisture loss through the skin.

5.2 Pharmacokinetic properties

- (a) General characteristics
- | | |
|-------------------|----------------|
| absorption | Not applicable |
| distribution | Not applicable |
| biotransformation | Not applicable |
| elimination | Not applicable |
- (b) Characteristics in patients
- Not applicable

5.3 Preclinical safety data

None available

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Nipasept comprised of:
Methyl parahydroxybenzoate (E218)
Ethyl parahydroxybenzoate (E214)
Propyl parahydroxybenzoate (E216)
Purified Water Ph. Eur.

6.2 Incompatibilities

This product should not be used to dilute steroid cream or ointments.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.

Keep the container tightly closed.

6.5 Nature and contents of container

100g in 150ml white polypropylene jar with white polypropylene lid.
500g in 650ml white polypropylene jar with white polypropylene lid.

Not all pack sizes may be marketed.

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

Ovelle Limited
Industrial Estate
Coe's Road
Dundalk
Co Louth
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0206/020/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 April 1989

Date of last renewal: 20 April 2009

10 DATE OF REVISION OF THE TEXT

December 2017