

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Oilatum Plus Bath Additive Light liquid paraffin 52.5% w/w Benzalkonium chloride 6.0% w/w Triclosan 2.0% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

| | | |
|-----------------------|------|-------|
| Light liquid paraffin | 52.5 | % w/w |
| Benzalkonium chloride | 6.0 | % w/w |
| Triclosan | 2.0 | % w/w |

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Bath additive.

A clear, pale yellow oily solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of infected eczemas and eczemas at risk from infection.

4.2 Posology and method of administration

Oilatum Plus should always be diluted with water. It is an effective cleanser and should not be used with soap.

Bath: In an eight inch bath add 2 capfuls; in a four inch bath add 1 capful.

Infant bath: Add 1 ml (just sufficient to cover the bottom of the cap) and mix well with water.

Soak for 15 minutes, gently pat the skin dry with a clean towel. Use once daily.

4.3 Contraindications

Patients with known hypersensitivity to any of the ingredients should not use the product.

Not recommended for babies younger than 6 months.

4.4 Special warnings and precautions for use

Avoid contact of the undiluted product with the eyes.

Take care to avoid slipping in the bath.

4.5 Interaction with other medicinal products and other forms of interactions

None known.

4.6 Fertility, pregnancy and lactation

There are no restrictions on the use of Oilatum Plus in pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None known.

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

Accidental ingestion: Oilatum Plus is intended for topical use only. Ingestion may cause gastro-intestinal irritation with vomiting and diarrhoea. Vomiting may result in foam aspiration. In the case of accidental ingestion, give 1 to 2 glasses of milk or water. If a large quantity of the product is ingested, the patient should be observed in hospital and the use of activated charcoal may be considered.

If the undiluted product comes into contact with the eye, reddening and watering may occur. Eye irrigation should be performed for 15 minutes and the eye examined under fluorescein stain. If there is persistent irritation or any uptake of fluorescein, the patient should be referred for ophthalmological opinion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Benzalkonium chloride and triclosan are anti-bacterial agents with proven efficacy against *Staphylococcus aureus*, the principal causative organism in infected eczemas.

Light liquid paraffin is an emollient widely used in the treatment of eczema.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acetylated wool alcohols
Isopropyl palmitate
Oleyl alcohol
Macrogol lauryl ether

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions

6.5 Nature and contents of container

PVC or HDPE bottle containing 150ml, 250ml, 500ml or 1 litre fitted with a polypropylene screw cap.

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

Clonmel Healthcare Ltd
Waterford Road
Clonmel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0126/323/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 May 1989

Date of last renewal: 25 May 2009

10 DATE OF REVISION OF THE TEXT

November 2019