

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Oilatum Emollient 63.4% w/w Bath Additive

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Light Liquid Paraffin 63.4 % w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Bath additive

Pale yellow oily liquid bath additive with a faint perfume.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Oilatum Emollient is indicated in the treatment of contact dermatitis, atopic dermatitis, senile pruritis, ichthyosis and related dry skin conditions.

4.2 Posology and method of administration

Oilatum Emollient should always be used with water, either added to the water or applied to wet skin.

Adult Bath

Add 1-3 capfuls to an 8-inch (20cm) bath of water. Soak for 10-20 minutes. Pat dry.

Infant Bath

Add 1/2-2 capfuls to a small bath of water. Apply gently over entire body with a sponge. Pat dry.

Skin Cleansing

Rub a small amount into wet skin, rinse off and pat dry.

Where conditions permit, and particularly in cases of extensive areas of dry skin, Oilatum Emollient should be used as a bath oil, ensuring complete coverage by immersion.

In addition to the therapeutic benefits, this method of use provides a means of sedating tense patients, particularly relevant in cases of acute pruritic dermatoses where relaxation of tension appears to relieve symptoms.

4.3 Contraindications

Known hypersensitivity to the ingredients.

4.4 Special warnings and precautions for use

None.

4.5 Interaction with other medicinal products and other forms of interactions

None.

4.6 Fertility, pregnancy and lactation

There are no restrictions on the use of the product in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

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 HPRC 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

Light liquid paraffin exerts an emollient effect by forming an occlusive oil film in the stratum corneum. This prevents excessive evaporation of water from the skin surface, aiding hydration and lubrication.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acetylated lanolin alcohols
Isopropyl palmitate
Magrogol 400 dilaurate
Polyoxyethylene 40 sorbital septealeate
Perfume - floral spice

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

High density polyethylene bottles of 150ml, 250ml and 500ml capacity.

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

Patients should be advised to use care to avoid slipping in the bath.

If a rash or skin irritation occurs, treatment should be discontinued.

7 MARKETING AUTHORISATION HOLDER

Clonmel Healthcare Ltd
Waterford Road
Clonmel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0126/322/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1984

Date of last renewal: 01 October 2009

10 DATE OF REVISION OF THE TEXT

November 2019