

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Oilatum Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains Light Liquid Paraffin 6.0% w/w and White Soft Paraffin 15.0% w/w in a cream base.

Excipient(s) with known effect

Benzyl Alcohol 0.5%w/w

Cetostearyl alcohol

Potassium Sorbate

For the full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Cream.

A white to off white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Oilatum Cream is indicated in the treatment of contact dermatitis, atopic eczema, senile pruritus, ichthyosis and related dry skin conditions.

4.2 Posology and method of administration

Oilatum Cream may be used as often as required. Apply to the affected area and rub in well. It is especially effective after washing, when the sebum content of the stratum corneum may be depleted resulting in excessive moisture loss.

Oilatum Cream is suitable for use in adults, children and the elderly.

4.3 Contraindications

Should not be used in patients with known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Oilatum Cream should be used with caution in patients with a known sensitivity or allergy to white soft paraffin or light liquid paraffin or to any of the excipients in the preparation.

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

This medicine contains 0.5% w/w benzyl alcohol which may cause allergic reactions and mild local irritation.

4.5 Interaction with other medicinal products and other forms of interactions

None.

4.6 Fertility, pregnancy and lactation

Fertility

There are no data on the use of topical Oilatum Cream on human fertility.

Pregnancy

There are no data on the use of topical Oilatum Cream in pregnant women. No effects during pregnancy are anticipated, since systemic exposure to white soft paraffin-light liquid paraffin is low.

Lactation

It is not known if Oilatum Cream is excreted in human milk. Risk to the infant is likely to be low since systemic exposure is low. Patients should be advised to ensure that any residual product is fully washed off the breast prior to breastfeeding.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

May cause irritation in patients hypersensitive to any of the ingredients.

Adverse drug reactions (ADRs) are listed below by MedDRA system organ and by frequency. Frequencies are defined as: very common ($\geq 1/10$), common ($\geq 1/100$ and $< 1/10$), uncommon ($\geq 1/1,000$ and $< 1/100$), rare ($\geq 1/10,000$ and $< 1/1,000$); very rare ($< 1/10,000$) and not known (cannot be estimated from the available data).

Post-marketing data***Skin and subcutaneous tissue disorders***

Rare: Application site reactions including application site erythema, rash, pain, pruritus, skin burning sensation.

Immune system disorders

Rare: Application site hypersensitivity reactions including application site dermatitis.

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, Website: www.hpra.ie

4.9 Overdose**Symptoms and signs**

The product is intended for topical use only. Ingestion may cause gastrointestinal irritation with nausea, vomiting and diarrhoea. Excessive topical application should cause no untoward effects other than greasy skin.

Treatment

In case of accidental ingestion, management should be as clinically indicated or as recommended by the national poisons centre, where available.

5 PHARMACOLOGICAL PROPERTIES**5.1 Pharmacodynamic properties**

Light Liquid Paraffin and White Soft Paraffin exert an emollient effect by forming an occlusive film which reduces trans-epidermal water loss, thus helping to maintain normal skin humidity levels. Polyvinyl pyrrolidone enhances the strength and longevity of the occlusive film formed by the oil on the skin.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

White Soft Paraffin and Light Liquid Paraffin have been used in pharmaceutical and cosmetic preparations for many years. The formulation contains excipients that are commonly used in such preparations. The safety of these substances is well established by common use over long periods in man.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 1000 Monostearate
Cetostearyl alcohol
Glycerol
Potassium sorbate
Benzyl alcohol
Citric acid monohydrate
Povidone
Purified water

6.2 Incompatibilities

None.

6.3 Shelf life

Three years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Internally lacquered, membrane sealed aluminium tubes fitted with a polypropylene screw cap and packed into a carton. Pack sizes of 40g and 80g.

Internally lacquered, membrane sealed aluminium tube fitted with a polyethylene screw cap and packed into a carton. Pack sizes 30g and 50g.

Laminate tube with polypropylene cap packed into carton. Pack sizes 100g and 150g.

High density polyethylene tube. Pack sizes 25 g, 50 g and 150 g.

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

None.

7 MARKETING AUTHORISATION HOLDER

Clonmel Healthcare Ltd
Waterford Road
Clonmel, Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0126/321/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 7 March 2003.

Date of last renewal: 7 December 2010

10 DATE OF REVISION OF THE TEXT

November 2020