

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Oilatum Fragrance Free

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Light Liquid Paraffin 63.4% w/w.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Bath Additive

Pale yellow, odourless, oily liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

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

Adult or Child Bath

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

Infant Bath

Add ½ - 2 capfuls to a basin of water. Apply gently over entire body with a sponge. Pat dry.

Skin Cleansing

Rub a small amount of oil into wet skin. Rinse and pat dry.

Oilatum Fragrance Free is most effective when it is used as a bath additive, particularly when the area of skin to be treated is extensive. In addition to its therapeutic benefits of hydration and emolliency, this method of use is particularly relevant in management of acute pruritic dermatoses where relaxation of tension appears to relieve symptoms.

Oilatum Fragrance Free acts as a skin cleanser, and should not be used with soap.

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 interaction

None.

4.6 Pregnancy and lactation

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

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None.

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

Oilatum Fragrance Free is a topical preparation which acts at the surface of the skin. Pharmacokinetic data are not applicable to this preparation.

5.3 Preclinical safety data

The active ingredient, light liquid paraffin, has been in widespread use for many years. Clinical experience has demonstrated the safety of the preparation. Pre-clinical safety data are not relevant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acetylated Wool Alcohols
Isopropyl Palmitate
Macrogol 400 Dilaurate
Polyoxyethylene 40 Sorbital Septaoleate

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 150 ml and 300 ml, fitted with screw caps.

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.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 144/22/5

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 10 December 2004

10 DATE OF REVISION OF THE TEXT

July 2006