Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Oilatum Junior Emollient Bath Additive

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Paraffin, Light Liquid 63.4% w/w.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Bath additive.
Pale yellow, odourless, oily liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

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

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

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

Oilatum Junior 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 the management of acute pruritic dermatoses where relaxation of tension appears to relieve symptoms.

Oilatum Junior acts as a skin cleanser, and should not be used with soap.
Patients should be advised to use care to avoid slipping in the bath. It is not necessary to use soap with Oilatum Junior.

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 Oilatum Junior in pregnancy and 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 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

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 Junior 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 Lanolin Alcohols
Isopropyl Palmitate
Macrogol 400 Dilaurate
Macrogol ester (Polyoxyethylene 40 Sorbital Septaoleate)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

High density polyethylene bottles of 25ml, 150ml and 300ml, 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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Clonmel Healthcare Ltd
Waterford Road
Clonmel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0126/322/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th February 1998.

Date of last renewal: 6th February 2008

10 DATE OF REVISION OF THE TEXT

November 2019