Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Oilatum Shower Gel 70% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of gel contains 700 mg light liquid paraffin equivalent to 70 % w/w.

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.

White, translucent, oily gel with an odour of perfume.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

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

4.2 Posology and method of administration

For cutaneous use only.

Oilatum Shower Gel may be used as frequently as necessary. Oilatum Shower Gel should always be applied to wet skin, normally as a shower gel.

Shower as usual. Apply Oilatum Shower Gel liberally to wet skin and massage gently. Rinse briefly and lightly pat the skin dry.

Oilatum Shower Gel is an effective cleanser and should be used instead of soap to cleanse the skin.

4.3 Contraindications

Hypersensitivity to light liquid paraffin or to any of the excipients in the preparation.

4.4 Special warnings and precautions for use

Use care to avoid slipping in the shower. Oilatum Shower Gel should not be used on greasy skin.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Fertility, pregnancy and lactation

Fertility
There are no data on the use of cutaneous light liquid paraffin on human fertility.

Pregnancy
No effects during pregnancy are anticipated, since systemic exposure to light liquid paraffin is expected to be low.

Lactation
It is not known if light liquid paraffin 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

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency. Frequencies are defined as: very common (≥1/10), common (≥1/100 and <1/10), uncommon (≥1/1,000 and <1/100), rare (≥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 irritation, rash, erythema, pruritus.

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 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

Symptoms and signs

The product is intended for cutaneous use only. Accidental ingestion may cause gastrointestinal irritation with nausea, vomiting and diarrhea.

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 exerts an emollient effect by forming an occlusive oil film on the stratum corneum. This prevents excessive evaporation of water from the skin surface thus improving hydration.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyethylene
Macrogol 400 Dilaurate
Macrogol Ester (Polyoxyethylene 40 Sorbitol Septaoleate)
2-Octadodecanol
Polypropylene glycol-2-Myristyl Ether Propionate
Polyphenylmethyl Siloxane Copolymer
Floral Spice

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

High-density polyethylene tubes of 25 g, 65 g, 125 g and 150 g.

Laminate tubes (polyethylene/ethylene vinyl alcohol copolymer (EVOH)/ polyethylene laminate, with a polyethylene shoulder) containing 30 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

No special requirements.

7 MARKETING AUTHORISATION HOLDER

GlaxoSmithKline Consumer Healthcare (Ireland) Limited
12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0678/113/003

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th June 1991

Date of last renewal: 10th June 2006

10 DATE OF REVISION OF THE TEXT

July 2015