# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Oilatum Junior Flare-Up Bath Additive Light liquid paraffin 52.5% w/w Benzalkonium chloride 6.0% w/w Triclosan

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Light liquid paraffin 52.5 %w/w
Benzalkonium chloride 6.0 %w/w
Triclosan 2.0 %w/w

Excipients with known effect
Acetylated wool alcohol 4.0 %w/w

For the full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Bath additive

Clear pale yellow oily solution.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

For the treatment of infected eczemas and eczemas at risk from infection.

### 4.2 Posology and method of administration

Posology
Oilatum Junior Flare-Up should always be diluted with water. It is an effective cleanser and should not be used with soap.

Paediatric Population
Not recommended for babies younger than 6 months.

Method of administration
Adults and children: In an eight inch bath add 2 capfuls, in a four inch bath add 1 capful.

Infants: Add 1 ml (just sufficient to cover the bottom of the cap) and mix well with water.

Soak for 15 minutes, gently pat the skin dry with a clean towel. Use once daily.

### 4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1

Not recommended for babies younger than 6 months.

### 4.4 Special warnings and precautions for use

Avoid contact of the undiluted product with the eyes.

Take care to avoid slipping in the bath.

The preparation should not be applied directly to the skin.

This medicinal product contains acetylated wool alcohol which may cause local skin reactions (e.g. contact dermatitis).

**4.5 Interaction with other medicinal products and other forms of interactions**

None known.

**4.6 Fertility, pregnancy and lactation**

There are no restrictions on the use of Oilatum Junior Flare-Up in pregnancy and lactation.

**4.7 Effects on ability to drive and use machines**

Oilatum Junior Flare-Up Bath Additive has no influence on the ability to drive and use machines.

**4.8 Undesirable effects**

Hypersensitivity reactions and contact dermatitis with triclosan, have been reported on occasions.

**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 the national reporting system:
HPRA Pharmacovigilance
Website: www.hpra.ie

**4.9 Overdose**

Accidental ingestion: Oilatum Junior Flare-Up is intended for topical use only. Ingestion may cause gastro-intestinal irritation with vomiting and diarrhoea. Vomiting may result in foam aspiration. In the case of accidental ingestion, give 1 to 2 glasses of milk or water. If a large quantity of the product is ingested, the patient should be observed in hospital and the use of activated charcoal may be considered.

If the undiluted product comes into contact with the eye, reddening and watering may occur. Eye irrigation should be performed for 15 minutes and the eye examined under fluorescein stain. If there is persistent irritation or any uptake of fluorescein, the patient should be referred for ophthalmological opinion.

**5 PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

**Pharmacotherapeutic group:** Soft paraffin and fat products, ATC code: D02AC

Benzalkonium chloride and triclosan are anti-bacterial agents with proven efficacy against Staphylococcus aureus, the principal causative organism in infected eczemas.

Light liquid paraffin is an emollient widely used in the treatment of eczema.

**5.2 Pharmacokinetic properties**

Not applicable.

**5.3 Preclinical safety data**

Not applicable.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Acetylated wool alcohols
Isopropyl palmitate
Oleyl alcohol
Macrogol lauryl ether

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

3 years.

### 6.4 Special precautions for storage

No special precautions for storage.

### 6.5 Nature and contents of container

White HDPE bottle containing 150ml or 300ml, fitted with a screw cap.

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal

No special requirements.

## 7 MARKETING AUTHORISATION HOLDER

Clonmel Healthcare Ltd
Waterford Road
Clonmel
Co. Tipperary
Ireland

## 8 MARKETING AUTHORISATION NUMBER

PA0126/323/001

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 May 1989

Date of last renewal: 19 March 2009

## 10 DATE OF REVISION OF THE TEXT

June 2021