

## **1 NAME OF THE MEDICINAL PRODUCT**

Oilatum Plus  
Oilatum Junior Flare-Up  
Oilatum Antiseptic Bath Emollient

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Light liquid paraffin 52.5% w/w, benzalkonium chloride 50% solution 12.0% w/w\*,  
triclosan 2% w/w

\*equivalent to 6% benzalkonium chloride

Excipient(s) with known effect  
Acetylated Lanolin Alcohols  
For the full list of excipients, see section 6.1.

## **3 PHARMACEUTICAL FORM**

Bath additive

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

Topical as a bath additive.

For the prophylactic treatment of eczemas at risk from infection.

### **4.2 Posology and method of administration**

For cutaneous use only.

Oilatum Plus must always be used diluted in water. It is an effective cleanser and should not be used with soap.

Use once daily. Do not exceed the recommended dose:

**Adults, adolescents and children:**In an eight inch bath (20 cm) add 2 capfuls (20 ml); in a four inch (10 cm) bath add 1 capful (10 ml). Mix well.

Soak for 10-15 minutes. Gently pat the skin dry with a clean towel.

**Infants over 6 months of age:** Add 1 ml (just sufficient to cover the bottom of the cap) to a baby bath containing approximately 15 litres of water and mix well. Soak for 10-15 minutes. Gently pat the skin dry with a clean towel.

The safety and efficacy of Oilatum Plus has not been established in children less than 6 months of age. Oilatum Plus is not recommended for use in children under 6 months of age.

**Elderly:** No dosage adjustment is required in the elderly.

#### 4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1

#### 4.4 Special warnings and precautions for use

Oilatum Plus contains benzalkonium chloride which is irritant and may cause skin reactions.

Contains Lanolin which may cause local skin reactions (e.g. contact dermatitis).

Keep out of reach and sight of children.

If irritation or rash occurs when the product is used in the correct dilution, use should be discontinued.

If the undiluted product comes into contact with the eye, reddening may occur. The patient should be advised to perform eye irrigation for 15 minutes. If there is persistent irritation the patient should be advised to contact a doctor.

Avoid contact of the undiluted product with the eyes and skin.

If undiluted product is applied directly to the skin, it may cause application site skin irritation and hypersensitivity reactions including skin exfoliation, pain, blister, caustic injury and necrosis. The patient should be advised to contact a doctor.

The patient should be advised to use care to avoid slipping in the bath.

Instruct patients not to smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

None known.

#### **4.6 Fertility, pregnancy and lactation**

##### **Fertility**

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

##### **Pregnancy**

No effects on pregnancy are anticipated, since systemic exposure to Oilatum Plus is expected to be low.

##### **Lactation**

It is not known if Oilatum Plus 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 breast-feeding.

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

None known.

#### **4.8 Undesirable effects**

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency. Frequencies are defined as not known (cannot be estimated from the available data).

##### **Post-marketing data**

##### **Skin and subcutaneous tissues disorders**

Not Known: Application site reactions including- skin exfoliation, erythema, dermatitis, pruritus and burning sensation.

##### **Immune System disorders**

Not known: Application site hypersensitivity

### **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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

## **4.9 Overdose**

Oilatum Plus is intended for cutaneous use only. Accidental ingestion may cause gastrointestinal irritation with nausea, vomiting and diarrhoea. It may also cause oesophageal erosion and necrosis.

Oilatum Plus is unlikely to have any systemic effects. Using more frequently than recommended may cause skin irritation and rash (see 4.8 Undesirable effects). 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**

ATC Code

Pharmacotherapeutic Group: Dermatologicals, other emollients and protectives

ATC code: D02AX

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

Benzalkonium chloride is a quaternary ammonium antiseptic and disinfectant.

Triclosan is a chlorinated bisphenol antiseptic.

Benzalkonium chloride is bactericidal against Gram-positive and, at higher concentrations, against some Gram-negative organisms.

Triclosan is effective against Gram-positive and most Gram-negative bacteria.

Both benzalkonium chloride and triclosan have proven efficacy against *Staphylococcus aureus*, the principal causative organism in infected eczemas.

### **5.2 Pharmacokinetic properties**

There have been no studies to investigate the pharmacokinetics of light liquid paraffin, benzalkonium chloride or triclosan when administered as Oilatum Plus. However, studies of benzalkonium chloride alone and triclosan alone showed minimal absorption. Light liquid paraffin is chemically and biologically inert.

The potential for systemic absorption of Oilatum Plus from a bath additive containing 52.5% w/w light liquid paraffin, 6% w/w benzalkonium chloride and 2.0% w/w of triclosan is expected to be low.

### **5.3 Preclinical safety data**

#### Benzalkonium chloride

Skin irritation and ocular irritation were noted when benzalkonium chloride was tested at concentrations greater than 0.1%. Benzalkonium chloride was not mutagenic in bacterial assays but was clastogenic in some *in vitro* mammalian assays. There was no evidence of carcinogenicity in lifetime dermal testing in mice and rabbits.

#### Triclosan

Triclosan is not reported to be genotoxic in bacterial and mammalian test systems.

#### Reproduction

There are no data on the effect of cutaneous application of light liquid paraffin, benzalkonium chloride, triclosan on embryo-fetal development or fertility.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Acetylated lanolin alcohols  
Isopropyl palmitate  
Oleyl alcohol  
Polyoxyethylene lauryl ether

### **6.2 Incompatibilities**

Benzalkonium chloride solution is inactivated by inorganic compounds including soaps and must not be mixed with other anionic surfactants.

### **6.3 Shelf life**

**a) For the product as packaged for sale**

3 years

**b) After first opening the container**

Comply with expiry date

**6.4 Special precautions for storage**

None.

**6.5 Nature and contents of container**

White polyvinyl chloride or high density polyethylene bottles containing 20ml, 25ml, 150ml, 250ml, 350ml, 500ml, 600ml, 1000ml with white polypropylene cap.

**6.6 Special precautions for disposal**

There are no special instructions for use or handling of Oilatum Plus/Oilatum Junior Flare-Up

**7 MARKETING AUTHORISATION HOLDER**

Thornton & Ross Ltd.  
Linthwaite,  
Huddersfield,  
HD7 5QH, UK

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 00240/0462

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

16.02.90

**10 DATE OF REVISION OF THE TEXT**

20/06/2022