



## PRESCRIBING INFORMATION

### OILATUM<sup>®</sup>

Light Liquid Paraffin (LLP), 63.40% w/w

## Dermatological Shower and Bath Oil

GlaxoSmithKline Inc.  
7333 Mississauga Road  
Mississauga, Ontario  
L5N 6L4  
[www.stiefel.ca](http://www.stiefel.ca)

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# **OILATUM®**

Light Liquid Paraffin (LLP), 63.40% w/w

## **THERAPEUTIC CLASSIFICATION**

Dermatologicals, other emollients and protectives

## **INDICATIONS AND CLINICAL USE**

OILATUM® (Light Liquid Paraffin (LLP), 63.40% w/w) relieves dry, itchy, sensitive skin, softens and hydrates the skin and helps protect against further drying.

## **CONTRAINDICATIONS**

No contraindications identified.

## **WARNINGS AND PRECAUTIONS**

OILATUM® should be used with caution in patients with a known sensitivity to LLP or to any of the excipients in the preparation.

OILATUM® is for external use only. Patients should be advised to avoid contact with the eyes. If contact occurs, rinse with water. If skin irritation occurs, patients should discontinue use. Patients should be advised to consult a healthcare practitioner if symptoms worsen or last for more than 7 days.

### **Sexual Function/Reproduction**

There are no data on the use of cutaneous LLP on human fertility.

### **Special Populations**

**Pregnant Women:** No effects during pregnancy are anticipated, since systemic exposure to LLP is expected to be low

**Nursing Women:** It is not known if LLP 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.

## **ADVERSE REACTIONS**

Adverse drug reactions (ADRs) are listed below by MedDRA system organ class and by frequency. Frequencies are defined as: very common ( $\geq 1/10$ ), common ( $\geq 1/100$  and  $< 1/10$ ), uncommon ( $\geq 1/1,000$  and  $< 1/100$ ), rare ( $\geq 1/10,000$  and  $< 1/1,000$ ); very rare ( $< 1/10,000$ ) and not known (cannot be estimated from the available data).

### **Post-Market Adverse Drug Reactions**

#### **Immune system disorders**

Rare: Application site hypersensitivity reactions including application site dermatitis

#### **Skin and subcutaneous tissue disorders**

Rare: Application site reactions including application site irritation, rash erythema, pruritus.

## **DRUG INTERACTIONS**

No drug interaction studies have been conducted with cutaneous OILATUM®. Considering the low level of systemic absorption, drug interactions are unlikely to occur.

## **DOSAGE AND ADMINISTRATION**

For cutaneous use only.

OILATUM® should always be used with water, either added to bath water, applied to wet skin or used as a shower gel.

OILATUM® is an effective cleanser and should be used instead of soap to cleanse the skin.

OILATUM® may be used as frequently as necessary.

## **Adults, adolescents and children**

### **Shower oil**

Shower as usual. Apply OILATUM® to wet skin and massage gently. Rinse briefly and gently pat the skin dry with a clean towel.

### **Bath additive**

In an eight inch (20 cm) bath of water add 10-20 mL and mix well.

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

Guard against slipping in tub or shower.

In cases of extensive areas of dry skin ensure complete coverage by immersion.

For skin cleansing, apply a small amount of OILATUM® additive onto wet skin. Rinse and gently pat the skin dry with a clean towel.

## **Infants**

### **Bath additive**

Add 5-10 mL to a basin of water (approximately 15 litres). Apply over entire body with a sponge. Gently pat the skin dry with a clean towel.

## **SYMPTOMS AND TREATMENT OF OVERDOSAGE**

OILATUM® is intended for cutaneous use only. Accidental ingestion may cause gastrointestinal irritation with nausea, vomiting and diarrhoea.

In case of accidental ingestion management should be as clinically indicated or as recommended by the regional Poison Control Centre.

For management of a suspected overdose, contact your regional Poison Control Centre.

## **DESCRIPTION AND COMPOSITION**

OILATUM® contains light liquid paraffin 63.40% w/w. OILATUM® also contains fragrance floral-spice, isopropyl palmitate, lanolin alcohol acetylated, PEG 40 sorbitan peroleate, and polyethylene glycol 400 dilaurate.

## **AVAILABILITY**

OILATUM® (Light Liquid Paraffin (LLP), 63.40% w/w) is available in a 250 mL bottle.