

*For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory*

## **OILATUM CREAM**

### **1. GENERIC NAME**

Light Liquid Paraffin and White Soft Paraffin Cream

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Light Liquid Paraffin IP	6.0% w/w
White Soft Paraffin IP	15.0% w/w
As preservatives:	
Benzyl Alcohol IP	0.5% w/w
Potassium Sorbate IP	0.2% w/w
in a cream base	

#### ***List of Excipients***

PEG 1000 Monostearate, Cetostearyl Alcohol, Citric Acid Monohydrate, Potassium Sorbate, PVP- K 30/Kollidon 30/Povidone, Benzyl Alcohol, Glycerin and Purified Water.

### **3. DOSAGE FORM AND STRENGTH**

Cream

For information on strength refer 2. *Qualitative and Quantitative Composition* above

### **4. CLINICAL PARTICULARS**

#### **4.1 Therapeutic Indication**

*OILATUM CREAM* is indicated for the treatment of contact dermatitis, atopic eczema, senile pruritus, ichthyosis and related dry skin conditions.

#### **4.2 Posology and Method of Administration**

*OILATUM CREAM* may be used as often as required. Apply to the affected area and rub in well. It is especially effective after washing when the sebum content of the stratum corneum may be depleted resulting in excessive moisture loss.

*OILATUM CREAM* is suitable for adults, children and the elderly.

### **4.3 Contraindications**

Should not be used in patients with known hypersensitivity to any of the ingredients.

### **4.4 Special Warnings and Precautions for Use**

*OILATUM CREAM* should be used with caution in patients with a known sensitivity or allergy to white soft paraffin or light liquid paraffin or to any of the excipients in the preparation.

Cetostearyl alcohol and potassium sorbate may cause local skin reactions (e.g. contact dermatitis).

This medicine contains 0.5% w/w benzyl alcohol which may cause allergic reactions and mild local irritation.

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 Drug Interactions**

None.

### **4.6 Use in Special Populations**

#### ***Fertility***

There are no data on the use of topical *OILATUM CREAM* on human fertility.

#### ***Pregnancy***

There are no data on the use of topical *OILATUM CREAM* in pregnant women. No effects during pregnancy are anticipated, since systemic exposure to *OILATUM CREAM* is low.

#### ***Lactation***

It is not known if *OILATUM CREAM* 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

## **4.8 Undesirable Effects**

May cause irritation in patients hypersensitive to any of the ingredients.

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-marketing data***

#### ***Skin and Subcutaneous Tissue Disorders***

Rare: Application site reactions including application site erythema, rash, pain, pruritus, skin burning sensation.

#### ***Immune System Disorders***

Rare: Application site hypersensitivity reactions including application site dermatitis

## **4.9 Overdose**

### ***Symptoms and signs***

The product is intended for topical use only. Ingestion may cause gastrointestinal irritation with nausea, vomiting and diarrhoea. Excessive topical application should cause no untoward effects other than greasy skin.

### ***Treatment***

In case of ingestion, management should be as clinically indicated or as recommended by the national poisons centre, where available.

## **5. PHARMACOLOGICAL PROPERTIES**

### **5.1 Mechanism of action /Pharmacodynamic Properties**

Light Liquid Paraffin and White Soft Paraffin exert an emollient effect by forming an occlusive film which reduces trans-epidermal water loss, thus helping to maintain normal skin humidity levels. Polyvinyl pyrrolidone enhances the strength and longevity of the occlusive film formed by the oil on the skin.

## 5.2 Pharmacokinetic Properties

Not applicable.

## 6. NONCLINICAL PROPERTIES

### 6.1 Animal Toxicology or Pharmacology

White Soft Paraffin and Light Liquid Paraffin have been used in pharmaceutical and cosmetic preparations for many years. The formulation contains excipients that are commonly used in such preparations. The safety of these substances is well established by common use over long periods in man.

## 7. DESCRIPTION

Cream

Light Liquid Paraffin IP	6.0% w/w
White Soft Paraffin IP	15.0% w/w
As preservatives:	
Benzyl Alcohol IP	0.5% w/w
Potassium Sorbate IP	0.2% w/w
in a cream base	

### *List of Excipients*

PEG 1000 Monostearate, Cetostearyl Alcohol, Citric Acid Monohydrate, Potassium Sorbate, PVP- K 30/Kollidon 30/Povidone, Benzyl Alcohol, Glycerin and Purified Water.

## 8. PHARMACEUTICAL PARTICULARS

### 8.1 Incompatibilities

No data available.

### 8.2 Shelf Life

The expiry date is indicated on the label and packaging.

### 8.3 Packaging Information

Lami Tube with plastic cap packed in a carton.

## **8.4 Storage and Handling Instructions**

Store at temperature below 25°C. Do not freeze.

Keep out of reach of children.

For external use only.

## **9. PATIENT COUNSELLING INFORMATION**

Registered Medical Practitioners may counsel their patients (and/or patient's caregiver as applicable) about the special warnings and precautions for use, drug interactions, undesirable effects, and any relevant contra-indications of *OILATUM CREAM*. Patients (and/or patient's caregiver) may also be informed about posology, method of administration and storage/handling information as applicable.

## **10. DETAILS OF MANUFACTURER**

The Manufacturing Site details are mentioned on the label and packaging.

### **For further information please contact:**

GSK Pharma India Private Limited,

### **Registered office :**

01, Battery House,

Bhulabhai Desai Road,

Mumbai- 400026

## **11. DETAILS OF PERMISSION OR LICENCE NUMBER WITH DATE**

Manufacturing License number is indicated on the label and packaging.

## **12. DATE OF REVISION**

12-JUN-2023

*Trade marks are owned by or licensed to the GSK group of companies.*

*Version: OLC/PI/IN/2023/01*

*Adapted from Oilatum Cream (tube) SmPC (last updated on emc: 8 Feb 2021). Available at:*  
<https://www.medicines.org.uk/emc/product/5453/>