For the use only of Registered Medical Practitioners or a Hospital or a Laboratory

EMODERM CREAM

1. GENERIC NAME

White Soft Paraffin Cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Emollient Cream base containing Benzoic Acid I.P. 0.2% w/w
(as preservative)

3. DOSAGE FORM AND STRENGTH

Cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the treatment of contact dermatitis, atopic eczema, senile pruritus, ichthyosis and related dry skin conditions.

4.2 Posology and Method of Administration

For topical use only. May be used as frequently as necessary.

Adults, adolescents and children

Apply to the skin as required and smooth into the skin in the direction of hair growth.

Elderly

No dosage adjustment is necessary.

Renal impairment

No dosage adjustment is necessary.
Systemic exposure to white soft paraffin is expected to be low following topical administration because percutaneous absorption of white soft paraffin is very low. (See section *5.3 Pharmacokinetic properties*)

Hepatic impairment

No dosage adjustment is necessary.
Systemic exposure to white soft paraffin is expected to be low following topical administration because percutaneous absorption of white soft paraffin is very low.

4.3 Contraindications

No contraindications identified.

4.4 Special Warnings and Precautions for Use

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

4.5 Drug Interactions

No drug interaction studies have been conducted with topical white soft paraffin. Considering the low level of systemic absorption, drug interactions are unlikely to occur.

4.6 Use in Special Populations

Fertility

No data available on the use of *EMODERM CREAM* on human fertility.

Pregnancy

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

Lactation

It is not known if white soft 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 breast-feeding.

4.7 Effects on Ability to Drive and Use Machines

There have been no studies to investigate the effect of *EMODERM CREAM* on driving performance or the ability to operate machinery. No effects are anticipated based on the adverse event profile.

4.8 Undesirable Effects

Adverse drug reactions (ADRs) are listed below by MedDRA system organ 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 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.

Treatment

In case of ingestion, management should be as clinically indicated.

5. PHARMACOLOGICAL PROPERTIES

5.1 Mechanism of Action

White soft paraffin is an emollient widely used in the treatment of eczema and related dry skin conditions.

5.2 Pharmacodynamic Properties

Pharmacotherapeutic Group: Dermatologicals, other emollients and protectives; ATC code : D02AX

Pharmacodynamic Effects
White soft paraffin exerts an emollient effect by forming an occlusive film on the stratum corneum.

5.3 Pharmacokinetic Properties

There have been no studies to investigate the pharmacokinetics of topically applied white soft paraffin. White soft paraffin is chemically and biologically inert. Penetration of the skin of mineral oil hydrocarbons does not go beyond the stratum corneum, and therefore systemic uptake of white soft paraffin is considered to be minimal (<1%).

6. NON-CLINICAL PROPERTIES

6.1 Animal Toxicology and Pharmacology

Carcinogenesis/mutagenesis
Genotoxicity and carcinogenicity studies have not been conducted.

White soft paraffin

Studies in which refined mineral oils were applied topically to the skins of mice, rats or rabbits, over periods of time ranging from 90 days to lifetime exposure have shown that white mineral oil does not produce tumours in any internal organ or at the site of application.
Repeat dose studies using mice, rats and rabbits showed that after 90 days or lifetime application of mineral oil, no histopathological changes to any internal organs or to the skin could be recognized that could be attributable to the chemical.
When administered orally over a prolonged period, white mineral oils induced pathological changes in the livers and mesenteric nodes of experimental animals.

Reproductive Toxicology

Fertility
There are no data on the effect of topical white soft paraffin on fertility.

Pregnancy
There are no data on the effect of topical white soft paraffin on pregnancy.

7. DESCRIPTION

Cream

Emollient Cream base containing Benzoic Acid I.P. 0.2% w/w
(as preservative)

8. PHARMACEUTICAL PARTICULARS

List of Excipients

White Soft Paraffin, Stearyl Alcohol, Cetyl Alcohol, Polysorbate 60, Isopropyl Myristate, Propylene Glycol, Benzoic Acid, Glycerin, Perfume Compound FL B-99122, Purified water.

8.1 Incompatibilities

No incompatibilities have been identified.

8.2 Shelf Life

The expiry date is indicated on the label and packaging.

8.3 Packaging Information

Tube in a carton

8.4 Storage and Handling Information

Store in a cool place, at a temperature not exceeding 25^{o}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 their patient's parents) about the special warnings and precautions for use, drug interactions, undesirable effects, and any relevant contra-indications of *EMODERM CREAM*. Patients (and/or their patient's parents) 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:
GlaxoSmithKline Pharmaceuticals Limited.
Registered Office
Dr. Annie Besant Road, Worli
Mumbai 400 030, India.

11. DETAILS OF PERMISSION OR LICENSE NUMBER WITH DATE

Manufacturing License number is indicated on the label and packaging

12. DATE OF REVISION

26 FEB 2020

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

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Adapted from :

- *White soft paraffin-light liquid paraffin GDS Version 01 dated 24 September 2012.*