Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

E45 Cream White Soft Paraffin 14.5% w/w Light Liquid Paraffin 12.6% w/w Anhydrous Lanolin 1.0% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

White soft paraffin	14.5 % w/w
Light liquid paraffin	12.6 % w/w
Anhydrous lanolin	1.0 % w/w

Also contains:

Cetyl alcohol	0.5% w/w
Methyl Hydroxybenzoate (E218)	0.15% w/w
Proryl Hydroxybenzoate (E216)	0.04% w/w

3 PHARMACEUTICAL FORM

Cream
Smooth white or practically white cream with not more than a slight odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of dry skin conditions, where the use of an emollient is indicated, such as flaking, chapped skin, ichthyosis, dermatitis, sunburn, the dry stage of eczema and for the use as emollient adjunctive therapy in the treatment of dry cases of psoriasis.

4.2 Posology and method of administration

Posology
Adults, Children, Babies and the Elderly - Apply to the affected part two or three times daily.

Method of administration
For topical application.

4.3 Contraindications

Hypersensitivity to white soft paraffin, light liquid paraffin and anhydrous lanolin or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

For external use only.

If hypersensitivity occurs, such as a rash, use of the product should be discontinued.

May cause allergic reactions (possibly delayed), such as local skin reactions. If rash develops, use of the product should be discontinued.

Patients being dispensed or treated with large quantities (>100g) of any paraffin-based product should be advised to regularly change clothing, bedding or dressings impregnated with the product and keep away from naked flames as there is a fire hazard, and as such should avoid smoking.

The product should not be applied to the mucous membranes or to broken skin.

4.5 Interaction with other medicinal products and other forms of interaction

The absorption of topical minoxidil can be increased by concurrent topical soft paraffin. This could potentiate the hypotensive effects of vasodilators.

4.6 Fertility, pregnancy and lactation

Pregnancy
No effects during pregnancy are anticipated, since systemic exposure to white soft paraffin, liquid paraffin and lanolin is negligible.

As with all medicines, this product should be used with caution during pregnancy.

Breast-feeding
It is unknown whether white soft paraffin, light liquid paraffin and anhydrous lanolin metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded. Application of the product to the breast is not recommended during breast feeding.

Fertility
No data on human fertility are available.

4.7 Effects on ability to drive and use machines

This product has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Occasionally, hypersensitivity reactions, otherwise adverse effects are unlikely. Adverse events which have been associated with white soft paraffin, light liquid paraffin and anhydrous lanolin are given below, tabulated by system organ class and frequency.

Frequencies are defined as: Very common (≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100); Rare (≥1/10,000 and <1/1000); Very rare (< 1/10,000); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Events
Immune System Disorders	Not known	Hypersensitivity[1]
Respiratory, Thoracic and Mediastinal Disorders	Not known	Pneumonia lipoid
Skin and Subcutaneous Tissue Disorders	Not known	Acne

Description of Selected Adverse Reactions
[1] May take the form of an allergic rash. Should this occur, use of the product should be discontinued.

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 HPRA Pharmacovigilance. Website: www.hpra.ie;

4.9 Overdose

Symptoms
There have been no reports of overdosage with the use of white soft paraffin, light liquid paraffin and anhydrous lanolin.

Management
If accidental ingestion occurs, treatment should be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Dermatologicals; Emollients and Protectives; Soft Paraffin and Fat Products **ATC Code:** D02AC

Anhydrous lanolin, light liquid paraffin and white soft paraffin have emollient moisturising properties.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

There is no preclinical safety data of relevance to the consumer.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glyceryl monostearate
Cetyl alcohol
Sodium cetostearyl sulphate
Carbomer
Methyl hydroxybenzoate (E218)
Propyl hydroxybenzoate (E216)
Sodium hydroxide
Citric acid monohydrate
Purified water

6.2 Incompatibilities

Compatibility problems may be encountered with the stronger acids, calcium, magnesium and aluminium salts, quaternary compounds, acridines, basic dyestuffs and alkaloids.

6.3 Shelf life

3 years (polypropylene tubs/pots).

2 years (polyethylene tubes).

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

A polyethylene tube with membrane seal and plastic screw cap.
Pack sizes: 15 or 50 g.

A polypropylene securipot with a white polythene pilfer-proof screw cap.
Pack size: 125 g, 350 g, and 500 g.

A polypropylene securipot with a polythene pilfer-proof screw cap fitted with a HDPE or a polypropylene dispenser having a polythene covered follower plate.
Pack sizes: 500 or 900 g.

A pump-pack, made of polypropylene and polyethylene, consisting of a piston pump system with an airless dispenser.
Pack size: 500g.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

KARO PHARMA AB
Box 16184
103 24 Stockholm
Sweden

8 MARKETING AUTHORISATION NUMBER

PA22650/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1977

Date of last renewal: 6 June 2009

10 DATE OF REVISION OF THE TEXT

September 2022