Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Aqueous Cream
Emulsifying Wax 9% w/w, White Soft Parafin 15% w/w, Liquid Paraffin 6% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Emulsifying Wax BP 9.0%w/w
White Soft Paraffin BP 15.0%w/w
Liquid Paraffin Ph. Eur. 6.0%w/w

Excipient: Emulsifying wax (containing Cetostearyl alcohol and sodium lauril sulfate)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.
Smooth white homogenous, light cream with a faint characteristic odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

a) Moisturiser and emollient that soothes and helps to hydrate dry skin.

b) Soap substitute.

Eczema and other dry skin conditions.

4.2 Posology and method of administration

Apply as often as required to prevent itching and flaking dry skin.
Adults: as above
Babies: as above
Elderly: as above

4.3 Contraindications

Not to be used by persons known to be sensitive to the ingredients.

4.4 Special warnings and precautions for use

For external use only.
If there is no improvement or aggravation of the conditions occurs, consult your doctor. Contains Cetostearyl alcohol which may cause local skin reactions (e.g. stinging and contact dermatitis).
Sodium lauril sulfate (E487) may cause local skin reactions (such as stinging or burning sensation) or increase skin reactions caused by other products when applied on the same area.
Sensitivity to Sodium lauril sulfate (SLS) can vary according to body site, age and patient population as well as other factors such as hydration level, skin colour and disease. Patient populations with decreased skin barrier functions such as in atopic dermatitis are more sensitive to the irritant properties of SLS.
Paediatric population
Aqueous cream contains sodium lauril sulfate (E487) which may cause local skin reactions (e.g. stinging and contact dermatitis), particularly in children with atopic eczema.
Healthcare professionals should be aware that if this product comes into contact with dressings, clothing and bedding, the fabric can be easily ignited with a naked flame. Patients should be warned of this risk and advised to keep away from fire when using this product.

4.5 Interaction with other medicinal products and other forms of interactions

None.

4.6 Fertility, pregnancy and lactation

Aqueous Cream is a monograph of the BP 1993 and as such

a) No animal reproduction/fertility study was carried out.

b) No study was carried out.

c) No known reason for not using in fertile, pregnant or lactating women.

4.7 Effects on ability to drive and use machines

1. Presumed to be safe and unlikely to produce an effect.

2. N/A.

3. N/A.

4.8 Undesirable effects

Allergic reaction to phenoxyethanol, which is rarely experienced.

Occasional allergic reactions. Aqueous cream may be associated with immediate cutaneous reactions when used as a leave-on emollient, such as stinging, burning, itching and redness. See section 4.4.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

N/A.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: D02AX Other emollients and protectives
- Emollient.
- The fats and oils in Aqueous Cream BP form a layer on the skin to help prevent moisture loss through the skin.

5.2 Pharmacokinetic properties

a) General

- absorption N/A
- distribution N/A
- biotransformation N/A
- elimination N/A

b) Characteristics in Patients

- Not applicable.

5.3 Preclinical safety data

Monograph of the BP 1993 and historically in many editions.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenoxyethanol
Purified water

6.2 Incompatibilities

Since Aqueous Cream contains an anionic surfactant it should not be used to dilute steroid creams or ointments.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.
Keep container tightly closed.

6.5 Nature and contents of container

White polypropylene jar with white polypropylene lid containing 100g of cream.

White polypropylene jar with white polyethylene lid containing 500g of cream.

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

Ovelle Ltd.
Industrial Estate
Coe's Rd
Dundalk
Co. Louth
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0206/021/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th November 1988

Date of last renewal: 18th November 2008

10 DATE OF REVISION OF THE TEXT

January 2019