

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Aqueous Cream B.P.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<u>Active ingredient</u>	<u>% w/w</u>
White Soft Paraffin BP	15.0
Liquid Paraffin BP	6.0

This product contains sodium lauryl sulphate (0.9% w/w), cetostearyl alcohol and chlorocresol, see section 4.4.

For a full list of excipients, section 6.1.

3. PHARMACEUTICAL FORM

Cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For topical application to the skin:

As an emollient for the symptomatic relief of dry skin conditions.

As a soap-substitute for skin washing

4.2 Posology and method of administration

Adults, children and elderly:

To be applied to the skin as required.

4.3. Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

For external use only.

Paediatric population

Aqueous cream contains sodium lauryl sulfate which may cause local skin reactions (e.g. stinging and contact dermatitis), particularly in children with atopic eczema.

An audit of children attending a paediatric dermatology clinic recorded the proportion of immediate cutaneous reactions to emollients (defined as one or more of burning, stinging, itching and redness developing within 20 minutes of application). Aqueous cream was the emollient used by most (71%), which was associated with an immediate cutaneous reaction in 56% of exposures, compared with 18% with other emollients used (details of the other emollients were not reported; $n = 100$).

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.

The package leaflet/label should include the following information:

Contains sodium lauryl sulfate and cetostearyl alcohol which may cause local skin reactions (e.g. stinging and contact dermatitis)

Contains chlorocresol which may cause allergic reactions

Keep all medicines out of the sight and reach of children.

4.5. Interactions with other medicinal products and other forms of interaction

No clinically significant drug interactions known.

4.6. Pregnancy and lactation

The safety of aqueous cream during pregnancy and lactation has not been established but is not considered to constitute a hazard during these periods.

4.7. Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

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 the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9. Overdose

Symptoms of accidental oral ingestion may include gastrointestinal symptoms, particularly diarrhoea. Treatment need only be symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

White soft paraffin and liquid paraffin have emollient properties.

5.2. Pharmacokinetic properties

None applicable.

5.3. Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Emulsifying wax (contains cetostearyl alcohol and sodium lauryl sulfate)
Chlorocresol
Purified water

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

36 months.

6.4. Special precautions for storage

Tub: Store in a cool place.

Tube: None

6.5 Nature and contents of container

Polypropylene jar with an unlined polypropylene cap.

Pack size: 500g

or Polypropylene securitub with a white pilfer-proof cap.

Pack size: 500g

or Pigmented LDPE/HDPE tube fitted with a polypropylene screw cap

Pack sizes: 60g 100g

or Laminate tube fitted with a polypropylene screw cap.

Pack sizes: 60g, 100g

6.6 Special precautions for disposal

Not applicable

7 MARKETING AUTHORISATION HOLDER

The Boots Company PLC

1 Thane Road West

Nottingham NG2 3AA

Trading as: BCM

8. MARKETING AUTHORISATION NUMBER

PL: 00014/5202R.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First Authorisation: 16th December 1986.

Renewal: 16th December 1991.

10 DATE OF REVISION OF THE TEXT

09/09/2019