

1 NAME OF THE MEDICINAL PRODUCT

Crescent Pharma Cetrимide Antiseptic 0.5% w/w Cream
Well Pharmaceuticals Antiseptic 0.5% w/w Cream
Crescent Pharma Antiseptic First Aid 0.5% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Cetrимide 0.50 % w/w

Excipients with known effect:

Cetostearyl Alcohol 5.0 % w/w

Ethyl parahydroxybenzoate (E214) 0.032 % w/w

Propyl parahydroxybenzoate (E216) 0.016 % w/w

Methyl parahydroxybenzoate (E218) 0.124 % w/w

Butyl parahydroxybenzoate 0.032 % w/w

Isobutyl 4-hydroxybenzoate 0.016 % w/w

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

Smooth opaque white cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

An antiseptic cream for chapped hands, minor skin abrasions, minor cuts and nappy rash.

4.2 Posology and method of administration

For all ages.

Method of administration

For general use, clean surrounding skin and apply cetrimide cream directly or on a piece of clean lint or gauze.

4.3 Contraindications

Hypersensitivity to cetrimide or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

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.

For external use only.

Prolonged and repeated applications of cetrimide are inadvisable as hypersensitivity may occur.

Avoid contact with the eyes.

This medicine may cause local skin reactions (e.g. contact dermatitis) as it contains cetostearyl alcohol.

This medicine may cause allergic reactions (possibly delayed) as it contains E214, E216 and E218.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Fertility, pregnancy and lactation

No special precautions.

4.7 Effects on ability to drive and use machines

No or negligible influence.

4.8 Undesirable effects

Hypersensitivity reactions may occasionally occur in certain individuals and present as localised contact dermatitis.

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

Overdosage with Cetrimide Cream is extremely unlikely. The ingestion of very large quantities of cetrimide and other quaternary ammonium compounds can cause nausea, vomiting, dyspnoea, cyanosis, CNS depression (sometimes preceded by excitement and convulsions), hypotension and coma. The fatal dose of quaternary ammonium compounds has been estimated to be 1 to 3 grams (equivalent to 200 – 600 grams of Cetrimide Cream 0.5% w/w).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

D08A J04 – Antiseptics & Disinfectants Quaternary Ammonium Compounds
Contains Cetrimide which is a topical disinfectant.

5.2 Pharmacokinetic properties

Not applicable.

6.3 Shelf life

24 months.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Liquid Paraffin

Cetostearyl Alcohol

Salinip [containing Phenoxyethanol, Methyl parahydroxybenzoate (E218), Ethyl parahydroxybenzoate (E214), Butyl parahydroxybenzoate, Iso butyl 4-hydroxybenzoate, Propyl parahydroxybenzoate (E216)]

Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

15g, 30g, 45g, 50g and 60g lacquered aluminium tubes with HDPE cap.

6.6 Special precautions for disposal

Customers are advised that the product is for external use only and to keep all medicines out of the reach of children.

7 MARKETING AUTHORISATION HOLDER

Crescent Pharma Limited

Key House, Sarum Hill,

Basingstoke,

RG21 8SR

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 20416/0282

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

27/01/2025

10 DATE OF REVISION OF THE TEXT

28/10/2025