

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

CRYSTACIDE CREAM 1%

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient

Hydrogen peroxide 1.0% (w/w)

1g of cream contains 10mg of hydrogen peroxide at a concentration of 1%.

3 PHARMACEUTICAL FORM

Cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Crystacide cream is intended for topical application for the treatment of primary and secondary superficial skin infections caused by organisms sensitive to hydrogen peroxide.

4.2 Posology and method of administration

Adults, elderly and children

Crystacide cream is applied 2-3 times daily on the infected skin area. The treatment period should not exceed 3 weeks. A dry film will appear on the skin after application, this can be washed off with water.

4.3 Contraindications

Hypersensitivity to the active substance or any of the excipients.

4.4 Special warnings and precautions for use

Contact with the eyes should be avoided. Crystacide Cream should not be used on large or deep wounds and should not be applied to healthy skin. Hydrogen peroxide can bleach fabric.

Salicylic acid is a mild irritant and can cause dermatitis. Crystacide Cream also contains propylene glycol which may cause skin irritation.

4.5 Interaction with other medicinal products and other forms of interaction

Crystacide cream is incompatible with iodine, permanganates and other stronger oxidising agents.

4.6 Fertility, Pregnancy and lactation

To be used under medical guidance.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8. Undesirable effects

A mild sensation of burning may be experienced for a short time after application.

Reporting of side effects

If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

4.9 Overdose

Not applicable

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: D0 8A

Antiseptics and Disinfectants

Hydrogen peroxide is a well-known antiseptic agent, and is effective against a majority of pathogenic micro-organisms.

In-vitro pharmacology studies have shown that hydrogen peroxide has both activity against a wide variety of micro-organisms, and is a potent antibacterial agent with effect against Gram-positive as well as Gram-negative bacteria.

In-vitro studies have shown that the bactericidal activity of Crystacide cream 1% is equal in effect compared with a 1% aqueous solution of hydrogen peroxide, and the duration of action is longer for the cream.

There are no known pathogenic bacteria or fungi that develop resistance to hydrogen peroxide.

5.2 Pharmacokinetic properties

Reports on the rate of absorption, distribution and excretion of hydrogen peroxide after oral administration are sparse. In the absence of stabilising agent, hydrogen peroxide gradually decomposes to oxygen and water. The decomposition is rapid in the presence of the endogenous enzyme catalase or peroxidase.

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

Glyceryl monolaurate
Glyceryl monomyristate
Macrogolstearate 5000
Propylene glycol
Citric acid anhydrous
Sodium hydroxide
Sulphuric acid, 1M
Sodium oxalate
Salicylic acid
Disodium edetate
Sodium pyrophosphate
Sodium stannate
Purified water

6.2 Incompatibilities

Iodine, permanganates and other stronger oxidising agents.

6.3 Shelf life

Unopened: 2 years

After first opening the container: 28 days

6.4 Special precautions for storage

Store below 25°C, in a dry place.

6.5 Nature and contents of container

Crystacide cream is filled into polyethylene tubes pigmented with titanium dioxide, and fitted with polypropylene caps. Each tube is subsequently packed in a unit, printed boxboard carton, in pack sizes of 5g, 10g, 25g and 40g.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 44095/0011

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17/01/2006

10 DATE OF REVISION OF THE TEXT

25/09/2019