Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Drapolene Cream Benzalkonium chloride 0.01% w/w Cetrimide 0.2% w/w

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

DRAPOLENE Cream contains
benzalkonium chloride 0.01 % w/w
(as benzalkonium chloride solution 0.02% w/w)
and Cetrimide 0.2% w/w.

Excipients with known effect:
Wool Fat (purified lanolin) 2.0 % w/w
Cetyl Alcohol 5.0 % w/w
Cetostearyl alcohol 4.0 % w/w
Chlorocresol 0.1 % w/w

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cream
A smooth homogenous pink water miscible cream for topical application.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

DRAPOLENE Cream is indicated for the prevention and treatment of urinary ammonia dermatitis, particularly nappy rash, and in the treatment of minor burns and wounds.

4.2 Posology and method of administration

Posology:

Children: Nappy rash. For topical application. To be applied evenly at each nappy change, particular attention being paid to the folds of the skin.

Adults: Urinary Dermatitis. Regular routine application is advised.

Use in the Elderly: No special comment

Minor burns and wounds: Apply as required.

Before applying Drapolene Cream, the affected area should be dry and free from all traces of soap.

Method of administration: Topical

4.3 Contraindications

DRAPOLENE Cream is contraindicated in patients with a hypersensitivity to the active substance or to any of the excipients (see section 4.4 and 6.1).

4.4 Special warnings and precautions for use

DRAPOLENE Cream is for external use only.

Not for application to mucosa.

Drapolene Cream contains wool fat (purified lanolin), cetyl alcohol and cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis) in some people.
Drapolene Cream also contains chlorocresol which may cause allergic reactions in some people.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Use during pregnancy and lactation is not expected to be associated with harmful effects to the mother as cutaneous absorption of benzalkonium chloride is minimal.

When used in accordance with the specified indications, systemic absorption of the specified components is not envisaged and so there are no special precautions/warnings appropriate to pregnancy and lactation.

You should not apply this medicine to the breasts if you are breast-feeding because the baby may take it in with your milk.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Frequency of adverse events cannot be estimated from available data.
If the condition is aggravated, application should be discontinued and the doctor consulted.
Allergic hypersensitivity reactions may occur in individuals who are sensitive to one or several components of Drapolene Cream.
Dermatitis as a result of contact allergy to benzalkonium chloride in plaster of Paris has also been reported.
Hypersensitivity, contact dermatitis and pruritus with cetrimide may occur.

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

There are no reports of adverse events resulting from excessive application or accidental ingestion of Drapolene Cream. In cases of accidental ingestion, symptomatic treatment is appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC code; D08AJ01 and D08AJ04. ANTISEPTICS AND DISINFECTANTS /Quaternary ammonium compounds

Benzalkonium chloride and cetrimide are both quaternary ammonium antiseptics/disinfectants with properties typical of cationic surfactants. This preparation is useful in the prevention and treatment of nappy rash, acting to suppress the development of ammonia producing organisms usually associated with this condition.

5.2 Pharmacokinetic properties

No data is available on the pharmacokinetics of the active ingredients of Drapolene Cream, when used for the specified indications. Systemic absorption of the active ingredients is not envisaged.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin and wool fat (purified lanolin) preblend
Cetyl alcohol
Emulsifying wax (contains cetostearyl alcohol)
Chlorocresol
Amaranth (E123)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

25g, 75g, 150g, 200g, 350g, in white polypropylene containers with white LDPE or LDPE/HDPE snap-fit caps.
500g in polypropylene pots with PVDC faced wad and polypropylene screw caps.

100 g in polyolefin/foil/polyolefin laminate tube with polypropylene caps.
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

Ravira Ltd
Aiolou 4,
3040, Limassol, Cyprus

8 MARKETING AUTHORISATION NUMBER

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1983
Date of last renewal: 01 April 2008

10 DATE OF REVISION OF THE TEXT

September 2022