SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Drapolene Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Drapolene contains:
Benzalkonium chloride solution 0.02% w/w

Equivalent to benzalkonium chloride 0.01% w/w

Cetrimide 0.2% w/w

3 PHARMACEUTICAL FORM

Cream for topical application

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Drapolene is indicated for the relief of nappy rash and for use as an adjunct to baby care hygiene for the prevention of nappy rash.

Drapolene is indicated for the relief of urinary dermatitis in adults, and as an adjunct to patient care hygiene for the prevention of urinary dermatitis.

Drapolene is indicated for the symptomatic relief of minor burns, limited sunburn and the effects of weather.

4.2 Posology and method of administration

Route of administration: Topical

Dosage:
Babies: The nappy area should be washed then dried thoroughly at each change of nappy. Drapolene Cream should be applied, paying particular attention to folds in the skin.

Adults: The affected area (or the area of application) should be washed and dried thoroughly before applying Drapolene. Regular routine application is advised.

Drapolene should be applied as required for minor burns, limited sunburn and the effects of weather.

Use in the Elderly:
No special comment

4.3 Contraindications

It is inadvisable to apply Drapolene Cream to a baby or adult who has an established hypersensitivity to benzalkonium chloride, cetrimide or lanolin. Use should be discontinued if an allergic hypersensitivity reaction is suspected.

4.4 Special warnings and precautions for use

The packs carry the following additional warnings:

Store below 25ºC

For external use only

Keep out of the reach of children

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, Pregnancy and lactation

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.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Allergic hypersensitivity reactions may occur in individuals who are sensitive to one or several components of Drapolene Cream.

Hypersensitivity to lanolin is recognised but is rare.

In a few individuals, benzalkonium chloride, used as a preservative in ophthalmic solutions, was associated with oedema and conjunctivitis. Dermatitis as a result of contact allergy to benzalkonium chloride in plaster of Paris has also been reported.

Hypersensitivity to cetrimide is also known to occur, presenting as a localised contact dermatitis. In severe cases the rash may be generalised.

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

Benzalkonium chloride and cetrimide are both quaternary ammonium disinfectants with properties typical of cationic surfactants. This preparation is useful in the treatment of and prevention 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
Wool fat (purified lanolin)
Cetyl alcohol
Polawax
Chlorocresol
Amaranth
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf life

Tube - 36 months unopened.

Other packs - 36 months unopened.

6.4 Special precautions for storage

Store below 25ºC.

6.5 Nature and contents of container

25, 75, 150, 200 or 350 g - white pigmented polypropylene containers with white pigmented LDPE snap-fit caps or white pigmented polypropylene containers with white pigmented LDPE/HDPE snap-fit caps.

500 g polypropylene pots with PVDC faced wad and polypropylene screw caps.

100 g polyolefin/foil/polyolefin laminate tubes with polypropylene caps.

6.6 Special precautions for disposal

None applicable.

7 MARKETING AUTHORISATION HOLDER

Ravira Ltd,

Markou Botsari 3,

3040, Limassol, Cyprus

8 MARKETING AUTHORISATION NUMBER(S)

PL 44543/0001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29/08/1989

10 DATE OF REVISION OF THE TEXT

27/01/2016