PACKAGE LEAFLET: INFORMATION FOR THE USER

Drapolene® Cream

Benzalkonium chloride 0.01% w/w, Cetrimide 0.2% w/w

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if the symptoms have not resolved or if the symptoms become worse.

What is in this leaflet:

1. What Drapolene® Cream is and what it is used for
2. What you need to know before you use Drapolene® Cream
3. How to use Drapolene® Cream
4. Possible side effects
5. How to store Drapolene® Cream
6. Contents of the pack and other information

1. What Drapolene® Cream is and what it is used for

Drapolene® Cream contains benzalkonium chloride and cetrimide in a non-greasy, soothing cream.

These are antiseptics that help stop bacteria growing.

Drapolene® Cream is used in the prevention, treatment and effective relief of nappy rash in babies, from newborn onwards.

Drapolene® Cream can also be used for adults with incontinence. It helps treat and soothe skin that is sore or likely to become sore because of urine on their skin (urinary dermatitis).

Drapolene® Cream can also be used to give soothing, effective relief from minor burns, such as mild sunburn and sore skin caused by the effects of weather.

You must talk to a doctor if the symptoms have not resolved or if the symptoms become worse.

2. What you need to know before you use Drapolene® Cream

Do not use Drapolene® Cream: If you are allergic (hypersensitive) to benzalkonium chloride or cetrimide or any of the other ingredients of this medicine (listed in section 6).

Other medicines and Drapolene® Cream: Drapolene® Cream is not known to interfere with other medicines.

Warnings and precautions whilst using Drapolene® Cream: Do not 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.

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

Drapolene® Cream contains: benzalkonium chloride, which may irritate the skin; wool fat (purified lanolin), cetyl alcohol and cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis); and chlorocresol which may cause allergic reactions.

3. How to use Drapolene® Cream

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The affected area should be washed and dried thoroughly. Apply Drapolene® Cream as required, paying particular attention to folds of the skin.

- **For nappy rash,** apply Drapolene® Cream evenly at each nappy change, having first cleaned and dried the nappy area.
- **For urinary dermatitis,** regular application is advised to prevent, treat and soothe soreness.
- **For minor burns,** including sunburn and weather effects, apply as required.

If the skin condition does not improve or becomes worse, talk to your doctor, pharmacist or nurse.

If you use more Drapolene® Cream than you should:

Using too much cream will not cause harm. If the cream is accidentally eaten, tell your doctor or go to the Accident and Emergency department of your nearest hospital.

If you forget to use Drapolene® Cream:

Use the cream as soon as you remember.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Drapolene® Cream can cause side effects such as skin rash or itching, but these are not common.

If you or your child feels ill after using Drapolene® Cream, or you notice any unusual or unexpected symptoms, tell your doctor or pharmacist straightaway.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly in the UK 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.

5. How to store Drapolene® Cream

Keep this medicine out of the sight and reach of children.

Store below 25°C.

Do not use this medicine after the expiry date which is stated on the label after "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Drapolene® Cream contains:

- The active substances are: benzalkonium chloride 0.01% w/w (as benzalkonium chloride solution 0.02% w/w) and cetrimide 0.2% w/w.
- The other ingredients are: white soft paraffin and wool fat (purified lanolin), cetyl alcohol, emulsifying wax (containing cetostearyl alcohol), chlorocresol, amaranth (E123), and purified water.

What Drapolene® Cream looks like and contents of the pack

Drapolene® Cream is a smooth, pink cream.

It comes in a 100g or 200g tube, or a 25g, 75g, 150g, 200g, 350g or 500g tub.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Ravira Ltd., Aiolou 4, 3020, Limassol, Cyprus.

Manufacturer

Laleham Health and Beauty Ltd., Sycamore Park, Alton, Hampshire, GU34 2PR, UK.

Distributor

Supra Enterprises Ltd., 2, Watergate Lane, The Green Warehouse, Leicester, LE3 2XP, UK.

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Drapolene® is a registered trade mark.

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