

Package leaflet: Information for the user

Sudosalve™

nappy rash treatment
0.15%w/w cream

Dibrompropamidine isetionate

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 any side effects occur, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4
- You must talk to a doctor or pharmacist if you do not see any improvement or if the symptoms worsen after a few days.

What is in this leaflet

- 1. What Sudosalve is and what it is used for**
- 2. What you need to know before using Sudosalve**
- 3. How to use Sudosalve**
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1. What Sudosalve is and what it is used for

Sudosalve contains the active substance dibrompropamidine isetionate. This medicine belongs to a group of medicines called antiseptics which can kill certain types of bacteria and fungi.

Sudosalve is used to treat nappy rash.

It can also be used to treat cuts, grazes, minor burns and other minor skin infections and outer ear infections.

2. What you need to know before using Sudosalve

Do not use Sudosalve

If you or your baby are allergic to dibrompropamidine or any of the other ingredients of this cream (listed in section 6).

Warnings and precautions

Do not use the cream for more than a few days at a time, as long term use can interfere with healing. The cream should not be used for long periods on young children.

If you do not see any improvement or if the symptoms worsen after a few days, talk to your doctor or pharmacist.

Please tell your doctor or pharmacist if you or your baby have experienced allergies to creams or ointments in the past.

Other medicines and Sudosalve

Tell your doctor or pharmacist if your baby is taking, has recently taken or might take any other medicines. There are no known interactions with other medications.

Sudosalve contains methyl parahydroxybenzoate (E218), castor oil and cetostearyl alcohol

- Methyl parahydroxybenzoate (E218) may cause allergic reactions (possibly delayed).
- Castor oil may cause skin reactions
- Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

If you have been told by your doctor that you or your baby are allergic to methyl parahydroxybenzoate, castor oil or cetostearyl alcohol contact your doctor before using this medicine.

3. How to use Sudosalve

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.

Wash your hands each time before you use the cream. Apply a pea size amount of the cream onto the skin area to be treated. Wash your hands again when you are finished. Use the cream two or three times a day.

Accidental swallowing of the contents of the tube is unlikely to lead to any serious effects.

If you forget to use this cream

If you forget to apply the cream at the usual time, apply it when you remember, unless it is close to the time for the next application. Do not apply a double amount to make up for a forgotten application.

4. Possible side effects

Like all medicines, this cream can cause side effects, although not everybody gets them. If any of the following side effects occur stop using this cream and contact your doctor or pharmacist **immediately**:

- rash, itching or redness at or around the area being treated
- rash, itching or redness on your fingers and hands after using the cream.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sudosalve

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

Do not store above 25°C. Keep it in the original tube with the top screwed on. Do not use the cream after the expiry date, which is printed on the tube.

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 Sudosalve contains

This cream contains the active ingredient dibrompropamide isetionate 0.15%w/w. It also contains Castor oil - virgin, Cetostearyl alcohol, Polyethylene glycol 600 monostearate, Methyl parahydroxybenzoate (E218), Silicone MS antifoam A, Purified water.

What Sudosalve looks like and contents of the pack

Sudosalve is a smooth, white cream.

The cream is available in a 25g, 30g or 50g tube.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Manx Healthcare Ltd
Taylor Group House, Wedgnoek Lane,
Warwick, CV34 5YA, UK

Manufacturer

Beltapharm SpA
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