

PATIENT INFORMATION LEAFLET - INFORMATION FOR THE USER

Brulidine™ Cream

Dibrompropamidine isetionate 0.15%w/w

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription.

However, you still need to use Brulidine carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects get serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

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2. Before using Brulidine
3. How to use Brulidine
4. Possible side effects
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1. What Brulidine is and what it is used for

Brulidine cream 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.

Brulidine is used to treat cuts, grazes, minor burns and other minor skin infections, as well as nappy rash, rashes affecting the moustache and beard areas, outer ear infections and ringworm of the scalp.

2. Before using Brulidine

Do not use Brulidine:

If you are allergic (hypersensitive) to dibrompropamidine or any of the other ingredients of Brulidine Cream. See section 6 for other ingredients.

Take special care with Brulidine

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.

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

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. There are no known interactions with other medications.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medication.

If you are pregnant, or think you may be pregnant please ask your doctor or pharmacist before using the cream. It may not be suitable for you.

Driving and using machines

There are no known effects of this medicine on your ability to drive or use machinery.

Important information about some of the ingredients of Brulidine Cream

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

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

3. How to use Brulidine

Adults

Wash your hands each time before you use the cream. Apply a pea size amount of the cream to the area to be treated, either straight onto the skin, or on a light dressing. Wash your hands again when you are finished, unless you are treating the hands. Most patients use the cream two or three times a day.

There are no specific recommendations for use in the elderly and children.

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

If you forget to use Brulidine

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

(continued overleaf)

WIP URN	✓	050515-BR01-PIL-12
APPROVED URN	N/A	
Job		Brulidine Cream PIL - Side 1
Size		210 x 148mm
Date		5 May 2015
BOH Approval Date		
Saved as		13879/12 PIL S1.ai M1
Prints		1 Colour - Black

4. Possible side effects

Like all medicines, Brulidine can cause side effects, although not everyone gets them. If you experience any of the following side effects stop using the 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. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Brulidine

Keep out of 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Brulidine looks like and contents of the pack

This medicine 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.

The cream is available in a 25g, 30g or 50g tube. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Manufacturer

Beltapharm SpA
Via Stelvio 66, 20095 Cusano Milanino, Milan, Italy

Other Formats

To request a copy of this leaflet in Braille, large print or audio please call 01926 482511.

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WIP URN: 050515-BR01-PIL-12

MANX
Pharma

WIP URN	✓	050515-BR01-PIL-12
APPROVED URN	N/A	
Job		Brulidine Cream PIL - Side 2
Size		210 x 148mm
Date		5 May 2015
BOH Approval Date		
Saved as		13879/12 PIL S2.ai M1
Prints		1 Colour - Black