Preparation

Dovobet

IIE015-02 - 160 x 600 mm - Page 1 of 2

100%

• Before applying Dovobet to the scalp, comb
  If you have scalp psoriasis
  • After applying the gel, avoid contact with
  • In order to achieve optimal effect, it is
  • Do not worry if some gel accidentally gets on
  • Wash your hands well after using Dovobet.
  • Do not bandage, tightly cover or wrap the
  • Use only on your psoriasis and do not use on

Instructions for proper use

How to put on Dovobet: Cutaneous use.

Always use this medicine exactly as your

1. What is Dovobet® and what is it used for?

Dovobet® is a topical treatment of scalp psoriasis in adults and in the skin of others under medical supervision. It contains the active substance betamethasone, a corticosteroid drug, and calcipotriol, a vitamin D3 derivative. Dovobet contains a strong corticosteroid, the most powerful available, in combination with the vitamin D3 derivative calcipotriol. This combination is useful for treating scalp psoriasis in adults when other treatments have not worked.

Dovobet contains a strong corticosteroid (i.e., MFT) and calcipotriol in order to achieve the best possible effect with a reduced risk of side effects.

2. What you need to know before you use Dovobet®

• You should not use Dovobet if:
  • You have certain types of psoriasis: these
  • You have psoriasis involving the eyes or mouth
  • You have a history of skin infections caused by bacteria
  • You have certain disorders of the skin
  • Your skin becomes infected as you may need
  • you have a certain type of psoriasis called
  • you experience blurred vision or other visual
  • you have used this medicine for a long time
  • you have used this medicine for a long time
  • you have used this medicine for a long time
  • you have used this medicine for a long time
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3. How do you use Dovobet®

How to use Dovobet®:

Take your Dovobet® just before you wash your hair and wash your scalp immediately after application. For best results, let Dovobet remain on your scalp for at least 30 minutes before washing.

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4. Possible side effects

The following serious side effects have been reported:

SIDE EFFECTS

Driving and using machines

You should avoid driving and using machines if you are using Dovobet. If you are driving or using machines, ask your doctor or pharmacist if you think this medicine will affect your driving or machine operation.

5. How to store Dovobet®

Store below 25°C. Protect from light.

6. Contents of the pack and other information

• The pack contains:
  • The label and the leaflet
  • The bottle of Dovobet®
  • Dovobet® is not recommended for the use in
  • your skin becomes infected as you may need
  • you have a certain type of psoriasis called
  • you experience blurred vision or other visual
  • you have used this medicine for a long time
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7. What do you do if you think you are allergic to any of the ingredients?

If you think you are allergic to any of the ingredients, see the section on Side effects.

8. Overdose

If you take too much Dovobet, contact your doctor or pharmacist.

9. Further information

This leaflet has been written for you by the medicines information unit of GlaxoSmithKline. For more information, contact GlaxoSmithKline Plc, London, UK.

10. Additional information

This leaflet has been reviewed by an independent panel of healthcare professionals. If you have any questions, contact your doctor or pharmacist.

11. Legal information

This leaflet has been reviewed by an independent panel of healthcare professionals. If you have any questions, contact your doctor or pharmacist.

12. Contact details

If you have any questions, contact your doctor or pharmacist.

13. What information should I keep and what information should I discard?

Keep this leaflet. It will help you to understand the medicine and remind you about the important information. It will also help your doctor or pharmacist to advise you about any new developments regarding this medicine.

1. What is Dovobet® and what is it used for?

Dovobet® is a topical treatment of mild to moderate scalp psoriasis in adults. It contains the active substances betamethasone and calcipotriol. Betamethasone is a corticosteroid that can reduce inflammation, scaling and thickness of your skin. Calcipotriol is a vitamin D3 derivative that can reduce the thickness of the skin and reduce inflammation. In combination, betamethasone and calcipotriol can help to treat mild to moderate scalp psoriasis.

2. What you need to know before you use Dovobet®

• You should not use Dovobet if:
  • you have any further questions, ask your doctor, pharmacist or nurse.
  • This medicine has been prescribed for your scalp. Do not use it on other areas of your skin.
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6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Dovobet looks like and contents of the pack

Dovobet is an aerosolised solution, design to digit fix low-high accuracy of the impact. It is available in two forms: a high and a light aerosol polyethylene spray (4 ml). The active substances are:

Calcipotriol 50 μg/g and 0.5 mg/g, betamethasone 0.05 mg/g.

The product is available in 4 ml cans.

Marketing Authorization Holder and Manufacturer

The Marketing Authorization holder is LEO Pharma A/S, Industriparken 55, DK-2750 Ballerup, Denmark.

The manufacturer is LEO Laboratories Ltd, UK, 280 Theobald’s Road, London WC1X 8AL.

This medicinal product is approved in the following names:

Daivobet®, Dovobet®, Xamiol® gel.

Space for text: 2 X 67,5 x 580 mm.

Not all pack sizes may be marketed.

Pack sizes: 15 g, 30 g, 60 g, 80 g, 2 x 60 g, 2 x 80 g.

The bottles are placed in cartons.

The active substances are:
Calcipotriol (as monohydrate) and 0.5 mg of betamethasone (as dipropionate).

One gram of gel contains 50 micrograms of calcipotriol and betamethasone.

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