1. WHAT Dovobet® IS AND WHAT IT IS USED FOR

Dovobet® is used as topical treatment of scalp psoriasis in adults and on the skin of other body areas (excluding the lips). It is not used on the area of psoriasis (psoriasis vulgaris) in adults. Psoriasis is caused by your skin cells being produced too quickly. This causes redness, scaling and thickness of your skin.

Dovobet® contains calcipotriol and betamethasone. Calcipotriol helps to bring the rate of skin cell growth back to normal and betamethasone acts to reduce inflammation.

2. BEFORE YOU USE DOVOBET

Do not use Dovobet®

- if you are hypersensitive (hypersensitivity) to calcipotriol, betamethasone or any of the other ingredients of Dovobet®
- if you have problems with calcium levels in your body (calcium metabolism)
- if you have certain types of psoriasis: these are erythrodermic, exfoliative and pustular (ask your doctor)
- if you have serious liver or kidney disease.

As Dovobet® contains a strong steroid, do not use it on skin affected by:

- infections caused by viruses (e.g. cold sores or chicken pox)
- infections caused by bacteria
- infections caused by parasites (e.g. scabies)
- tuberculosis (TB) or syphilis
- parasitic infestations in and around the mouth
- thin skin, easily damaged veins, stretch marks
- ichthyosis (dry skin with fish-like scales)
- acne (pimples)
- rosacea (severe flushing or redness of the skin on the face)
- ulcers or broken skin.

- itch of the anus (back passage) or genitals (sex organs).

Take special care with Dovobet®

Before using Dovobet® for the first time, tell your doctor/nurse/pharmacist if:

- you have diabetes mellitus (diabetes) as your blood sugar/glucose level may be affected by the steroid
- you have liver disease or kidney disease.

Special precautions

- Avoid use on more than 30% of your body or using more than 15 grams per day.
- Do not use more than 4 g per day on areas of the skin that are easily stained by grease (e.g. silk).
- Do not bandage, tightly cover or wrap the treated skin area.
- Avoid use on the face, mouth and eyes.

Children

Dovobet® is not recommended for use in children under the age of 18 years.

3. HOW TO USE DOVOBET

How to put on Dovobet®: Cutaneous use.

- Squeeze the gel onto a clean finger or directly onto the scalp.
- Rub it well in using your fingertips, and rub it in gently.
- Avoid contact with your eyes.
- Avoid contact with mucous membranes.

- Wash your hands well after using Dovobet®. This reduces the risk of spreading the medicine to others.

- Do not use more than 15 grams in one day.
- Do not use more than 4 g per day on areas of the skin that are easily stained by grease (e.g. silk).
- Use the gel on skin affected by psoriasis.
- Do not take into the mouth.
- Do not take by mouth.

4. POSSIBLE SIDE EFFECTS

Lack of growth or pubic hair, excessive hair growth, increased risk of infection.

- With long-term treatment:

  - ulcers or broken skin
  - infections caused by bacteria
  - infections caused by parasites
  - ulcers or broken skin

- Excessive prolonged use of Dovobet® may also cause:

  - hypertrichosis (excessive hair growth).
  - acne (pimples)
  - rosacea (severe flushing or redness of the skin on the face).

- If you have any further questions about the use of this medicine, tell your doctor or pharmacist.
Some serious side effects are known to be caused by betamethasone (a strong steroid), one of the ingredients in Dovobet®. You should tell your doctor as soon as possible if any of the serious side effects occur. These side effects are more likely to happen after long-term use, or use under occlusion. The side effects include the following:

- Your adrenal glands may stop working properly.
- Swelling of the mouth/throat and trouble breathing may occur. If you have an allergic reaction, stop taking Dovobet®, tell your doctor immediately or go to the casualty department at your nearest hospital.
- Rash with inflammation of the skin (dermatitis)
- Eczema.
- Sensitivity of the skin to light resulting in a rash
- Inflammation or swelling of the hair root (folliculitis)
- Skin pain or irritation
- Burning sensation of the skin
- Itching.

Less serious side effects known to be caused by calcipotriol

- Allergic reactions with deep swelling of the face or other parts of the body such as the hands or feet.
- Swelling of the mouth/throat and trouble breathing may occur. If you have an allergic reaction, stop taking Dovobet®, tell your doctor immediately or go to the casualty department at your nearest hospital.
- Rash
- Dry skin
- Acne (pimples)
- Rash
- Pustular rash.

Less serious side effects caused by using betamethasone for a long time include the following, and you should tell your doctor or nurse as soon as possible if you notice any of them:

- Thinning of the skin
- Appearance of surface veins or stretch marks
- Changes in hair growth
- Red rash around the mouth (perioral dermatitis)
- Small white spots (colloid milia)
- Depigmentation (lightening of skin colour).

Less serious side effects known to be caused by using calcipotriol include the following:

- Allergic reactions with deep swelling of the face or other parts of the body such as the hands or feet.
- Rash
- Itching.

Common side effects (affect less than 1 in 10 people):

- Redness
- Burning sensation
- Swellings
- Itching
- Darkening of face
- Rash
- Burning of skin
- Hair loss
- Small white spots
- Thinning of skin
- Acne
- Soreness
- Redness
- Rash
- Itching.

6. FURTHER INFORMATION

What Dovobet® contains

The active substances are:

- Calcipotriol and betamethasone.
- The other ingredients are:
  - paraffin, liquid
  - polyoxypropylene-15 stearyl ether
  - castor oil, hydrogenated
  - butylhydroxytoluene (E321)
  - all-rac-α-tocopherol

What Dovobet® looks like and the contents of the pack

Dovobet® is an almost clear, colourless to slightly off-white gel filled in high-density polyethylene bottles with a low-density polyethylene nozzle and a high-density polyethylene screw cap. The bottles are placed in cartons.

Pack sizes: 15, 30, 60 and 2 x 60 g. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder is: LEO Pharma A/S Industrieparken 55 DK-2750 Ballerup Denmark

The manufacturer is: LEO Laboratories Ltd. (LEO Pharma) 285 Cashel Road Dublin 12 Ireland

For further information about this medicine, contact the local representative of the Marketing Authorisation Holder.

LEO Laboratories Limited, Princes Risborough, Bucks, HP27 9RR, U.K. Tel: (01844) 347333 e-mail: medical-info.uk@leo-pharma.com

This medicine is authorised in the Member States of the EEA under the following names:

- In the United Kingdom: Dovobet® gel: United Kingdom

This leaflet was last revised in: January 2012.

For further information about psoriasis, you can contact:

- The Psoriasis Association.
- mail@psoriasis-association.org.uk

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