

Dovobet[®] gel

calcipotriol/betamethasone

Read all of this leaflet carefully before you start using this medicine.

- **Keep this leaflet.** You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- **This medicine has been prescribed for you.** Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

There is information on the following

1. **What Dovobet[®] is and what it is used for**
2. **Before you use Dovobet[®]**
3. **How to use Dovobet[®]**
4. **Possible side effects**
5. **How to store Dovobet[®]**
6. **Further information**

1. WHAT DOVOBET[®] IS AND WHAT IT IS USED FOR

Dovobet[®] is used as topical treatment of scalp psoriasis and on the skin of other body areas to treat mild to moderate plaque psoriasis (psoriasis vulgaris). 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 **allergic (hypersensitive)** to calcipotriol, betamethasone or any of the other ingredients of Dovobet[®]
- If you have problems with **calcium levels** in your body (ask your doctor)
- If you have **certain types of psoriasis**: these are guttate, 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 a **fungus** (e.g. athlete's foot or ringworm)
- infections caused by **bacteria**
- infections caused by **parasites** (e.g. scabies)
- **tuberculosis (TB)** or **syphilis**
- **perioral dermatitis** (red rash 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**.
- itching of the **anus** (back passage) or **genitals** (sex organs).

Take special care with Dovobet[®]:

Before using this product, tell your doctor/nurse/pharmacist if:

- you are using other medicines that contain **corticosteroids** as you may get side effects
- you have used this **medicine for a long time and plan to stop** (as there is a risk your psoriasis will get worse or 'flare up' when steroids are stopped suddenly)
- you have **diabetes mellitus** (diabetes) as your blood sugar/glucose level may be affected by the steroid
- your **skin becomes infected** as you may need to stop your treatment.

Special precautions

- Avoid use on more than 30% of your body or using more than 100 grams per week
- Avoid using under a bathing cap, bandages or dressings as it increases the absorption of the steroid
- Avoid use on large areas of damaged skin or skin folds (groin, armpits, under breast) as it increases the absorption of the steroid
- Avoid use on your face or genitals (sex organs) as they are very sensitive to steroids
- Avoid excessive sunbathing, excessive use of solarium and other forms of light treatment

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.

Pregnancy and breast-feeding

Do not use Dovobet[®] if you are pregnant (or might be pregnant) or if you are breast-feeding, **unless you have agreed it with your doctor first**. If your doctor has agreed that you can breast-feed, take care and do not apply Dovobet[®] to the breast area.

Driving and using machines

This medicine should not have any effect on your ability to drive or use machinery.

Important information about some of the ingredients of Dovobet[®]

Dovobet[®] contains butylhydroxytoluene (E321), which may cause local skin reactions (e.g. contact dermatitis) or irritation to the eyes and mucous membranes.

3. HOW TO USE DOVOBET[®]

Always use Dovobet[®] exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How to put on Dovobet[®]: Cutaneous use.

Dovobet[®] is not recommended for the use in children and adolescents below the age of 18 years.

Instructions for proper use

- Use only on your psoriasis and do not use on skin which does not have psoriasis
- Shake the bottle before use and remove the cap
- Squeeze the gel onto a clean finger or directly onto the area affected by psoriasis
- Apply Dovobet[®] to the affected area with your fingertips, and rub it in gently until the area affected by psoriasis is covered by a thin layer of gel
- Do not bandage, tightly cover or wrap the treated skin area
- Wash your hands well after using Dovobet[®]. This will avoid accidentally spreading the gel to other parts of your body (especially the face, mouth and eyes)
- Do not worry if some gel accidentally gets on normal skin near your psoriasis, but wipe it off if it spreads too far
- After applying the gel, avoid contact with textiles which are easily stained by grease (e.g. silk).

If you have scalp psoriasis:

- Before applying Dovobet[®] to the scalp, comb the hair to remove any loose scales. Tilt your head to make sure Dovobet[®] does not run onto your face. It may help to part your hair before you use Dovobet[®]. Apply Dovobet[®] to the affected area with your fingertips, and rub it in gently
- For treatment of the scalp usually an amount between 1 g and 4 g per day is sufficient (4 g corresponds to one teaspoon)
- Washing your hair before application of Dovobet[®] is not necessary
- In order to achieve optimal effect, it is recommended that the hair is not washed immediately after application of Dovobet[®]. Let Dovobet[®] remain on the scalp during the night or during the day.

Duration of treatment

- Use the gel **once a day**. It may be more convenient to use the gel in the evening
- The normal initial treatment period is **4 weeks** for scalp areas and **8 weeks** for non-scalp areas
- Your doctor may decide on a different treatment period
- Your doctor may decide on repeated treatment.

Do not use

- **more than 15 grams in one day or**
- **100 grams in one week.**

If you use other calcipotriol containing products, the total amount of calcipotriol products must not exceed 15 grams per day or 100 grams per week and the area treated should not exceed 30% of the total body surface.

What should I expect when I use Dovobet[®]?

Most patients see obvious results after 2 weeks, even if the psoriasis is not yet cleared at that point.

If you have used more Dovobet[®] than you should

Contact your doctor if you have used more than **15 grams** in one day or **100 grams** in one week. Excessive prolonged use of Dovobet[®] may cause a problem with calcium in your blood, which usually goes back to normal when treatment is stopped. Your doctor may need to carry out blood tests to check that using too much gel has not caused a problem with calcium in your blood. Excessive prolonged use can also cause your adrenal glands to stop working properly (the adrenal glands are found near the kidneys and produce hormones).

If you forget to use Dovobet[®]

Do not use a double dose to make up for forgotten individual doses.

If you stop using Dovobet[®]

The use of Dovobet[®] should be stopped as indicated by your doctor. It may be necessary for you to stop this medicine gradually, especially if you have used it for a long time.

If you have any further questions about the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Dovobet[®] can cause side effects, although not everybody gets them.

Approximately 1 in 12 people may experience side effects, but most of these are reactions at the site where the gel has been applied.

Serious side effects:

Tell your doctor/nurse immediately or as soon as possible if any of the following happens. You may have to stop your treatment:

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 occur rarely but are **more likely** to happen **after long-term use**, or use under bathing caps, bandages or dressings. The side effects include the following:

- Your adrenal glands may stop working properly. Signs are tiredness, depression and anxiety
- Cataracts (signs are cloudy and foggy vision, difficulty seeing at night and sensitivity to light) or an increase in pressure inside your eye (signs are eye pain, red eye, decreased or cloudy vision)
- Infections (because your immune system, which fights infections, may be suppressed or weakened)
- Pustular psoriasis (a red area with yellowish pustules usually on the hands or feet). If you notice this, stop taking Dovobet® and tell your doctor as soon as possible.

Uncommon (affect less than 1 in 100 people):

- Worsening of your psoriasis. If your psoriasis gets worse, tell your doctor as soon as possible.

Very rare (affect less than 1 in 10,000 people):

- 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
- Treatment with this gel may cause the level of calcium in your blood or urine to increase (usually when too much gel has been used). Signs of increased calcium in blood are bone pain, constipation, poor appetite, nausea and vomiting. This can be serious, and you should contact your doctor immediately. However, when the treatment is stopped, the levels return to normal.

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)
- Skin rash with inflammation or swelling (allergic contact dermatitis)
- Small white spots (colloid milia)
- Depigmentation (lightening of skin colour).

The following less serious side effects have also been reported for Dovobet®:

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

- Itching.

Uncommon (affect less than 1 in 100 people):

- Eye irritation
- Burning sensation of the skin
- Skin pain or irritation
- Inflammation or swelling of the hair root (folliculitis)
- Rash with inflammation of the skin (dermatitis)
- Redness of the skin due to widening of the small blood vessels (erythema)
- Acne (pimples)
- Dry skin
- Rash
- Pustular rash.

Other less serious side effects, which have been reported, include:

- Sensitivity of the skin to light resulting in a rash
- Eczema.

Do not stop Dovobet® unless your doctor tells you to, as it may be necessary for you to stop this medicine gradually.

If you notice the above or any other changes in your health while taking this medicine, tell your doctor.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE DOVOBET®

- Keep out of the reach and sight of children
- Do not use Dovobet® after the expiry date which is stated on the bottle after EXP. The expiry date refers to the last day of that month
- Do not refrigerate. Keep the bottle in the outer carton in order to protect from light
- Discard the bottle with any remaining gel 3 months after first opening.

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 Dovobet® contains**

The **active substances** are:

Calcipotriol and betamethasone.
One gram of gel contains 50 microgram of calcipotriol (as monohydrate) and 0.5 mg of betamethasone (as dipropionate).

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 Pharmaceutical Products Ltd. A/S
DK-2750 Ballerup
Denmark

The **manufacturer** is:

LEO Pharmaceutical Products Ltd. A/S
DK-2750 Ballerup
Denmark

For further information about this product, contact the local representative of the Marketing Authorisation Holder:

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

UK: Dovobet® gel

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® Registered Trade Mark



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