

PACKAGE LEAFLET: INFORMATION FOR THE USER
Dovobet® 50micrograms/g & 0.5mg/g gel.
 (calcipotriol/betamethasone dipropionate)

This product will be referred to as Dovobet throughout the remainder of this leaflet.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

What is in this leaflet

1. What Dovobet is and what it is used for
2. What you need to know before you use Dovobet
3. How to use Dovobet
4. Possible side effects
5. How to store Dovobet
6. Contents of the pack and other information

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 to treat mild to moderate plaque 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.

Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Betamethasone is classed as a strong corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE DOVOBET®

Do not use Dovobet

- If you are allergic (hypersensitive) to calcipotriol, betamethasone or any of the other ingredients of this medicine (listed in section 6)
- If you have problems with calcium levels in your body (ask your doctor)
- If you have certain types of psoriasis: these are erythrodermic, exfoliative and pustular (ask your doctor).

As Dovobet contains a strong steroid do NOT use it on skin affected by

- skin infections caused by viruses (e.g. cold sores or chicken pox)
- skin infections caused by a fungus (e.g. athlete's foot or ringworm)
- skin infections caused by bacteria
- skin infections caused by parasites (e.g. scabies)
- tuberculosis (TB)
- 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.

Warnings and precautions

Talk to your doctor/nurse/pharmacist before and during use of Dovobet 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
- you have a certain type of psoriasis called guttate psoriasis.
- you experience blurred vision or other visual disturbances.

Special precautions

- Avoid use on more than 30% of your body or using more than 15 grams per day
- 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, on mucous membranes or in skin folds (groin, armpits, under breasts) 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.

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Children

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

Other medicines and Dovobet

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. 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 machines.

Dovobet contains butylated hydroxytoluene (E321)

Dovobet contains butylated hydroxytoluene (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 this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How to put on Dovobet: Cutaneous use.

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
- In order to achieve optimal effect, it is recommended not to take a shower or bath immediately after application of Dovobet gel
- 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.

Washing your hair before application of Dovobet is not necessary.

Shake bottle before use.



Apply a drop of Dovobet to fingertip.

Apply directly to scalp areas where you can feel the raised plaque and rub the Dovobet gel on to the skin

Depending on the affected area 1-4 g (up to 1 teaspoon) is normally enough.

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. When washing hair after application the following instructions might be useful:



Apply a mild shampoo to the **dry hair**, especially to those areas where the gel was applied.



Leave the shampoo on the scalp for a couple of minutes before washing.



Wash your hair as usual.

If necessary, repeat steps 4-6 once or twice.