

LEAFLET: INFORMATION FOR USERS

Dovobet 50 microgram/0.5 mg/g ointment
calcipotriol/betamethasone

Read the entire 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.

- Do you have any questions? Please contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet?
- Then contact your doctor or pharmacist. Contents of this leaflet

What is Dovobet and what is it used for?

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6. Contents of the package and other information

1. WHAT IS DOVOBET AND WHAT IS THIS MEDICINE USED FOR?

Dovobet ointment is used on the skin for the treatment of plaque psoriasis (psoriasis vulgaris) in adults. Psoriasis is caused by your skin cells being produced too quickly. This causes redness, scaling, and thickening of the skin.

Dovobet ointment contains calcipotriol and betamethasone. Calcipotriol helps to normalize the growth rate of skin cells and betamethasone has anti-inflammatory effects.

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR SHOULD YOU BE EXTRA CAUTIOUS?

When should you not use this medicine?

- if you are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.
- if you have problems with the calcium levels in your body (consult your doctor)
- if you have certain types of psoriasis such as erythrodermic psoriasis, exfoliative psoriasis, and pustular psoriasis (consult your doctor).

Dovobet contains a potent steroid, therefore DO NOT use it on skin affected by:

- skin infections caused by viruses (e.g., herpes or chickenpox)
- skin infections caused by fungi (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, fragile veins, stretch marks

- ichthyosis (dry skin with fish scales)
- acne (pimples)
- rosacea (severe flushing or redness of the facial skin)
- ulcers or skin wounds.

When should you be extra careful with this medicine?

Consult your doctor/nurse/pharmacist before using this product and during use when:

- you are using other medicines that contain corticosteroids because you may experience side effects from them
- you have used this medicine for a long time and plan to stop using it (because there is a risk that psoriasis may worsen or return when steroids are suddenly stopped)
- you have diabetes mellitus (diabetes) because your blood sugar/glucose level may be affected by the steroid
- a skin infection occurs, as it may be necessary to stop the treatment
- you have a certain form of psoriasis called psoriasis guttata
- you experience blurred vision or other vision problems.

Special warnings

- Avoid using on more than 30% of your body and do not use more than 15 grams per day
- Avoid using under bandages or dressings as this promotes the absorption of the steroid
- Avoid using on large affected areas, on mucous membranes, or in skin folds (groin, armpits, under the breasts) as this promotes the absorption of the steroid.
- Avoid using on the face or genitals (sex organs) as these are very sensitive to steroids
- Avoid excessive exposure to the sun, excessive use of tanning beds, or other forms of light therapy.

Children

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

Are you using any other medicines?

Are you using any other medicines besides Dovobet, have you recently done so, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor before using this medicine. If your doctor has agreed that you can breastfeed, be careful and do not apply Dovobet to the breasts.

Driving and using machines

This medicine has no effect on the ability to drive and use machines.

Dovobet ointment contains butylhydroxytoluene (E321)

Dovobet ointment contains butylhydroxytoluene (E321). This can cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

Where to apply Dovobet: use on the skin (cutaneous).

Instructions for correct use

- Use only on psoriasis patches and not on other parts of the skin that are not affected by psoriasis.
- Remove the cap and check that the seal is intact before using the ointment for the first time used
- Squeeze the ointment onto a clean finger
- Gently rub the ointment onto your skin on the psoriasis patches until most of the ointment is absorbed into the skin.
- Do not bandage, tightly cover, or wrap the treated skin.
- After applying Dovobet, wash your hands carefully (unless you are using the ointment to treat your hands). This prevents the ointment from accidentally getting on other parts of the body (especially the face, mouth, and eyes).
- After applying Dovobet, wash your hands carefully (unless you are using the ointment to treat your hands). This prevents the ointment from accidentally getting on other parts of the body (especially the face, mouth, and eyes).
- You do not need to worry if a little ointment accidentally gets on the unaffected skin next to the psoriasis patches, but wipe it off if it spreads too far.
- To achieve an optimal effect, it is recommended not to bathe or shower immediately after applying Dovobet ointment.
- After applying the ointment, avoid contact with materials sensitive to grease stains (e.g., silk).

Duration of treatment

- Use the ointment once a day. It may be more pleasant to use the ointment in the evening.
- The usual initial treatment period is 4 weeks, but your doctor may decide to change the treatment period.
- Your doctor may decide on a follow-up treatment.
- Do not use more than 15 g per day.

If you are also using other products containing calcipotriol, the total use of calcipotriol-containing products should not exceed 15 grams per day. The area being treated should not be larger than 30% of the total body surface.

What can I expect when using Dovobet?

Most patients see clear results after 2 weeks, even if the psoriasis is not yet gone at that time.

Have you used too much of this medicine?

Consult your doctor if you have used more than 15 grams per day.

Excessive use of Dovobet can also cause problems with the calcium in your blood, which usually normalizes when the treatment is stopped.

It may be necessary for your doctor to perform a blood test to check if using too much ointment has caused any problems with the calcium in your blood.

Excessive long-term use can also cause your adrenal glands to not work properly (the adrenal glands are located near the kidneys and they produce hormones).

Have you forgotten to use this medicine?

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

If you stop using this medicine

With the use of Dovobet must be stopped on the advice of your doctor. You may need to gradually stop using this medicine, especially if you have used it for a long period.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Contact your doctor or nurse immediately or as soon as possible if any of the following side effects occur. It may be necessary to stop the treatment: The following serious side effects have been reported for Dovobet Sometimes (occur in less than 1 in 100 users):

- Worsening of psoriasis. Inform your doctor immediately if psoriasis worsens.

Rarely (occur in less than 1 in 1000 users):

- Pustular psoriasis may occur (red skin area with yellowish pustules, usually occurs on hands or feet). If you notice this side effect, stop using Dovobet and inform your doctor as soon as possible.

Some serious side effects are caused by betamethasone (a potent steroid), one of the components of Dovobet. You should inform your doctor as soon as possible if any of these serious side effects occur. These side effects mainly occur after long-term use, use in skin folds (groin, armpits, under the breasts), use under occlusive dressing, or use on large skin areas. It concerns the following side effects:

- Adrenal glands not functioning properly. Symptoms include fatigue, depression and anxiety.
- Cataracts (symptoms include blurred vision, night blindness, and sensitivity to light) or increased pressure in the eye (symptoms include eye pain, red eye, reduced or blurred vision).
- Infections (because the immune system that fights infections is suppressed or weakened).
- Pustular psoriasis (red skin area with yellowish pustules, usually occurs on hands or feet). If you get this, stop using Dovobet and tell your doctor as soon as possible.
- Impact on the control of diabetes mellitus (if you have diabetes, you may experience fluctuations in your blood sugar levels)

Serious side effects caused by calcipotriol

- Allergic reactions with noticeable swelling of the face or other parts of the body such as the hands or feet. Swelling of the mouth/throat and breathing difficulties may occur.

If you have an allergic reaction, stop using Dovobet, inform your doctor immediately or go to the emergency department of the nearest hospital.

- During treatment with this ointment, the calcium level in your blood or urine may rise (usually if too much ointment was used). Symptoms of elevated calcium levels include excessive urine production, constipation, muscle weakness, confusion, and coma. This can be serious and you should immediately contact your doctor. When the treatment is stopped, the calcium level normalizes.

Less serious side effects

The following less serious side effects have been reported for Dovobet. Common (occur in less than 1 in 10 users):

- Itching
- Skin peeling.

Uncommon (occur in less than 1 in 100 users):

- Irritated or painful skin
- Skin rash with skin inflammation (dermatitis)
- Redness of the skin caused by vasodilation (erythema)
- Inflammation or swelling of the hair follicles (folliculitis)
- Skin discolorations at the site where you applied the ointment
- Skin rash
- Burning sensation
- Skin infection
- Thinning of the skin
- Red or purple discoloration of the skin.

Rare (occur in less than 1 in 1000 users):

- Bacterial or fungal infection of a hair follicle (boil)
- Allergic reactions
- Increased calcium levels in the blood (hypercalcemia)
- Stretch marks (striae)
- Sensitivity of the skin to light, resulting in a rash
- Acne (pimples)
- Dry skin
- Worsening of psoriasis after stopping treatment (rebound effect).

Unknown (cannot be determined from the available data)

- Blurred vision

Less serious side effects mainly caused by prolonged use of betamethasone are the following. Inform your doctor or nurse as soon as these occur.

- Thinning of the skin
- Appearance of dilated blood vessels or stretch marks
- Altered hair growth
- Red rash around the mouth (perioral dermatitis)
- Rash with inflammation or swelling (allergic contact dermatitis)
- Golden-colored gel-filled bumps (colloid milia)
- Lightening of the skin (depigmentation)
- Inflammation or swelling of the hair follicles (folliculitis).

Less serious side effects caused by calcipotriol are the following

- Dry skin
- Sensitivity of the skin to light, resulting in a rash.
- Eczema
- Itching
- Skin irritation
- Burning and stinging sensation
- Redness of the skin due to dilation of small blood vessels (erythema)
- Rash
- Rash with inflammation of the skin (dermatitis)
- Worsening of psoriasis.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date. It can be found on the packaging after EXP. It includes a month and a year. The last day of that month is the expiry date.
- Store below 25 °C.
- The tube must be discarded 1 year after first opening. Write the date you first opened the tube on the box.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. CONTENTS OF THE PACKAGING AND OTHER INFORMATION

What substances are in this medicine?

The active substances in this medicine are: calcipotriol and betamethasone.

One gram of ointment contains 50 micrograms of calcipotriol (as monohydrate) and 0.5 mg of betamethasone (as dipropionate).

The other substances in this medicine are:

- liquid paraffin
- all-rac- α -tocopherol
- polyoxypropylene stearyl ether
- white soft paraffin
- butylhydroxytoluene (E321).

What does Dovobet look like and what is in a package?

Dovobet ointment is an off-white to yellow-colored ointment in aluminum/epoxyphenol tubes with a polyethylene screw cap.

Package sizes: 15, 30, 60, 100, and 120 g.

Not all mentioned package sizes are marketed.

Marketing authorization holder and manufacturer The authorization holder is:

LEO Pharma A/S
Industriparken 55
2750 Ballerup
Denmark

The manufacturer is:

LEO Laboratories Ltd.
Cashel Road, Dublin 12,
Ireland.

For more information about this medicine, please contact the local representative of the authorization holder.

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Marketing authorization number: RVG 27095.

This medicine is registered in EEA member states under the following names:

Daivobet[®]: Bulgaria, Denmark, Germany, Estonia, Finland, France, Hungary, Latvia, Lithuania, Malta, Norway, Poland, Portugal, Romania, Slovenia, Spain, Czech Republic, Iceland, Sweden

Dovobet[®]: Belgium, Cyprus, Greece, Ireland, Italy, Luxembourg, Netherlands, United Kingdom

This leaflet was last approved in August 2022.

Detailed information about this medicine is available on the website of the Medicines Evaluation Board.