

PACKAGE LEAFLET: INFORMATION FOR THE USER

Daivobet[®] 50 micrograms/g + 0.5 mg/g ointment 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 become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See Section 4.

In this leaflet:

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

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

Daivobet[®] ointment is used on the skin to treat 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.

Daivobet[®] ointment 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 DAIVOBET

Do not use Daivobet[®]

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

As Daivobet[®] contains a strong steroid do NOT use 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 Daivobet®

Talk to your doctor/nurse/pharmacist before using Daivobet® 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 have serious liver or kidney disease.

Special precautions

- Avoid use on more than 30 % of your body or using more than 15 grams per day
- Avoid using under 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 breasts) as it increases the absorption of the steroid
- Avoid use on the 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.

Children

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

Other medicines and Daivobet®

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 Daivobet® 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 Daivobet® to the breast area.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

Important information about some of the ingredients of Daivobet® ointment

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

3. HOW TO USE DAIVOBET

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

How to put on Daivobet®: Cutaneous use.

Instruction for proper use

- Use only on your psoriasis and do not use on skin which does not have psoriasis
- Remove the cap and check that the seal in the tube is not broken before you first use the ointment
- To break the seal, use the point in the back of the cap

- Squeeze the ointment onto a clean finger
- Rub gently into your skin to cover the affected area of psoriasis until most of the ointment has disappeared into the skin
- Do not bandage, tightly cover or wrap the treated skin area
- Wash your hands well after using Daivobet[®] (unless you are using the ointment to treat your hands). This will avoid accidentally spreading the ointment to other parts of your body (especially the face, scalp, mouth and eyes)
- Do not worry if some ointment 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 Daivobet[®] ointment
- After applying the ointment avoid contact with textiles which are easily stained by grease (e.g. silk).

Duration of treatment

- Use the ointment once a day. It may be more convenient to use the ointment in the evening
- The normal initial treatment period is 4 weeks but 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.

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

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

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

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

Contact your doctor if you have used more than 15 grams in one day.

Excessive prolonged use of Daivobet[®] may cause a problem with calcium in your blood, which usually normalises when discontinuing treatment.

Your doctor may need to carry out blood tests to check that using too much ointment has not caused a problem with calcium in your blood.

Excessive prolonged use can also cause your adrenal glands to stop working properly (these are found near the kidneys and produce hormones).

If you forget to use Daivobet[®]

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

If you stop using Daivobet[®]

The use of Daivobet[®] 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 medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Approximately 1 in 10 people may experience side effects but most of these are reactions at the site where the ointment has been applied and are usually mild and temporary.

Serious side effects

The following serious effects have been reported for Daivobet[®]:

Uncommon (affects less than 1 in 100 people)

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

Rare (affects less than 1 in 1 000 people)

- Pustular psoriasis may occur (a red area with yellowish pustules usually on the hands or feet). If you notice this, stop taking Daivobet[®] and tell your doctor as soon as possible.

Some serious side effects are known to be caused by betamethasone (a strong steroid), one of the ingredients in Daivobet[®]. You should tell your doctor as soon as possible if any of the serious side effects occur:

- 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 the eye (signs are eye pain, red eye, decreased or cloudy vision)
- Infections (because your immune system which fights infections may be suppressed or weakened)
- Impact on the metabolic control of diabetes mellitus (if you have diabetes you may experience fluctuations in the blood glucose levels).

These side effects are more likely to happen after long-term use, use in skin folds (e.g. groin, armpits or under breasts), use under bandages or dressings or use on large areas of skin.

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 Daivobet[®], **tell your doctor immediately or go to the casualty department at your nearest hospital**
- Treatment with this ointment may cause the level of calcium in your blood or urine to increase (usually when too much ointment has been used). Signs of increased calcium in blood is bone pain, constipation, poor appetite, nausea and vomiting. **This can be serious and you should contact your doctor as soon as possible.** However, when the treatment is stopped, the levels return to normal.

Less serious side effects

The following less serious side effects have been reported for Daivobet[®]. If any of them last a long time or cause you problems, you should tell your doctor or nurse.

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

- Itching
- Rash
- Burning sensation.

Uncommon (affect less than 1 in 100 people)

- Skin pain or irritation
- Rash with inflammation of the skin (dermatitis)
- Redness of the skin due to widening of the small blood vessels (erythema)
- Inflammation or swelling of the hair root (folliculitis)
- Changes in skin colour in the area you have used the ointment.

Not known frequency

- Rebound effect: A worsening of symptoms/psoriasis after ended treatment.

Less serious side effects caused by using betamethasone, include the following. You should tell your doctor as soon as possible if you notice them.

- Thinning of the skin
- Appearance of surface blood vessels or stretch marks
- Changes in hair growth

- Red rash around the mouth (perioral dermatitis)
- Skin rash with inflammation or swelling (allergic contact dermatitis)
- Shiny brown gel-filled bumps (colloid milia)
- Lightening of skin colour (depigmentation).

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

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Bulgarian Drug Agency 8 Damyan Gruev Str.

Sofia 1303

Phone: +359 2 8903417

Website: www.bda.bg

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE DAIVOBET[®]

- Keep out of the reach and sight of children
- Do not use Daivobet[®] after the expiry date, which is stated on the label after EXP. The expiry date refers to the last day of that month
- Do not store the medicine above 25 °C
- The tube should be discarded 1 year after first opening. Write the date you first opened the tube in the space provided on the carton.

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 Daivobet[®] contains

The active substances 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 ingredients are:

- liquid paraffin
- all-rac- α -tocopherol
- polyoxypropylene-11-stearyl ether
- white soft paraffin.
- butylhydroxytoluene (E321)

What Daivobet[®] looks like and contents of the pack

Daivobet ointment is an off-white to yellow coloured ointment filled in aluminium/epoxyphenol tubes with polyethylene screw cap.

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation holder is:

LEO Pharma A/S
Industriparken 55
DK-2750 Ballerup
Denmark

The manufacturer is:

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

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

Borola Ltd.
Ovcha Koupel 2, bl. 2A Ground Floor
Sofia 1632
Bulgaria

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

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

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

This leaflet was last approved in

06/2013

Detailed information on this medicine is available on the web site of Bulgarian drug agency