

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### Daivobet® 50 micrograms/g + 0.5 mg/g 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:

1. What Daivobet is and what it is used for
2. Before you use Daivobet
3. How to use Daivobet
4. Possible side effects
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## 1. WHAT DAIVOBET IS AND WHAT IT IS USED FOR

Daivobet 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.

Daivobet 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
- 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 Daivobet 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 Daivobet**

Before using this medicine, 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
- 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 a batching 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 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.

### **Children**

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

### **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 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**

Daivobet 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 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.

### 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 Daivobet 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 Daivobet. 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 Daivobet 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 Daivobet to the scalp, comb the hair to remove any loose scales. Tilt your head to make sure Daivobet does not run onto your face. It may help to part your hair before you use Daivobet. Apply Daivobet 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 Daivobet is not necessary
- In order to achieve optimal effect, it is recommended that the hair is not washed immediately after application of Daivobet. Let Daivobet 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.

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 also 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 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 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 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.

The following serious side effects have been reported for Daivobet

Uncommon (affect less than 1 in 100 people)

- Worsening of your psoriasis. If your psoriasis gets worse, 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. 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. 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 Daivobet and tell your doctor as soon as possible
- Impact on the metabolic control of diabetes mellitus (if you have diabetes you may experience fluctuations in the blood glucose levels).

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 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 is 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

The following less serious side effects have been reported for Daivobet

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.

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).

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

- 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](http://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 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 Daivobet contains**

The active substances are :

Calcipotriol and betamethasone.

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

The other ingredients are:

- paraffin, liquid
- polyoxypropylene-11- stearyl ether
- castor oil, hydrogenated
- butylhydroxytoluene (E321)
- all-rac- $\alpha$ -tocopherol.

### **What Daivobet looks like and the contents of the pack**

Daivobet is an almost clear, colourless to slightly off-white gel filled in high-density polyethylene bottles with low-density polyethylene nozzle and a high-density polyethylene screw cap.

The bottles are placed in cartons.

Pack sizes: 15, 30, 60, 2 x 60 g and 3 x 60 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 Pharma A/S  
Industriparken 55  
DK-2750 Ballerup  
Denmark

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

Borola Ltd.  
z.k. Ovcha Kupel 2, bl. 2A Ground Floor  
Sofia 1632  
Bulgaria

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

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

Dovobet®: Belgium, Cyprus, Greece, Ireland, Italy, Netherland, Great Britain.

### **This leaflet was last approved in**

06/2013

Detailed information on this medicine is available on the web site of Bulgarian Drug Agency