Package leaflet: information for the user

Dovobet® 50micrograms/g+0.5mg/g Gel

(calcipotriol / betamethasone)

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. 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.

The name of your medicine is Dovobet® 50micrograms/g+0.5mg/g Gel but will be referred to as Dovobet throughout this leaflet.

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 vulgararis) 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.

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 Dovobet (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

Warning and precautions

Talk to your doctor/nurse/ pharmacist before using 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

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 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

Children

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

Other medicines and Dovobet

Please tell your doctor, pharmacist or nurse 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.

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 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.

<u>Instructions for proper use</u>
- 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
- After applying the gel, avoid contact with textiles which are easily stained by grease (e.g. silk).

<u>If you have scalp psoriasis</u>
- 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 1g and 4g per day is sufficient (4g 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.

<u>Duration of treatment</u>
- 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 15grams in one day.

If you use other calcipotriol containing medicines, the total amount of calcipotriol products must not exceed 15grams per day 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 15grams in one day. Excessive use of Dovobet 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 Dovobet
Do not take 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.

The following serious side effects have been reported for Dovobet

Uncommon (may affect up to 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 Dovobet. 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, use in skin folds (e.g. groin, armpits or under breasts), use under occlusion, or use on large areas of skin.

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 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)
- Pustular psoriasis (a red area with yellowish pustules usually on the hands or feet). If you notice this, stop using Dovobet 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 using 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 excessive secretion of urine, constipation, muscle weakness, confusion and coma. 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 Dovobet

Common side effects (may affect up to 1 in 10 people):
- Itching.

Uncommon (may affect up to 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
- Infection of the skin

Rare (may affect up to 1 in 1,000 people)
- Allergic reactions
- Stretch marks
- Skin exfoliation
- Rebound effect: A worsening of symptoms/psoriasis after ended treatment

Less serious side effects caused by using betamethasone, especially for a long time include the following. 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)
- Golden coloured gel-filled bumps (colloid milia)
- Lightening of skin colour (depigmentation)
- Inflammation or swelling of the hair root (folliculitis)

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
- Itching
- Skin irritation
- Burning and stinging sensation
- Redness of the skin due to widening of the small blood vessels (erythema)
- Rash
- Rash with inflammation of the skin (dermatitis)
- Worsening of psoriasis

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE DOVOBET
- Keep out of the sight and reach of children
- Do not use Dovobet after the expiry date, which is stated on the carton and bottle label after 'Exp'. The expiry date refers to the last day of that month.
- Do not refrigerate. Store in the original package in order to protect from light.
- Use the medicine within 3 months after first opening.
- If your medicine becomes discoloured or shows any signs of deterioration, you should seek the advice of your pharmacist. 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 50micrograms calcipotriol (as monohydrate) and 0.5mg betamethasone (as dipropionate).
The other ingredients are: liquid paraffin, polyoxypropylene-15 stearyl ether, hydrogenated castor oil, butylhydroxytoluene (E321) and alpha tocopherol.

What Dovobet looks like and the contents of the pack
Dovobet is an almost clear, colourless to slightly off-white gel contained in plastic bottle with a nozzle and a screw cap.
Dovobet is available in pack size of 30grams.

Manufactured by: Leo Pharmaceutical Products Ltd A/S, 55 Industriparken-2750 Ballerup, Denmark.
Or,
Leo Laboratories Ltd (Leo Pharma), 285 Cashel Road, Dublin 12, Ireland.

Procured from within the EU and repackaged by the PPA holder:
B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex, HA4 0NU, UK.

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