

PART III: CONSUMER INFORMATION**^{PR}DOVOBET® Gel
calcipotriol and betamethasone dipropionate gel**

This leaflet is part III of a three-part "Product Monograph" published when Dovobet® gel was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Dovobet® gel. Contact your doctor or pharmacist if you have any questions about this drug.

ABOUT THIS MEDICATION**What the medication is used for:**

Dovobet® gel is applied to the skin in the treatment of patients 18 years and older with:

- Moderate to severe psoriasis on the scalp for up to 4 weeks, and
- Mild to moderate psoriasis plaques on the body for up to 8 weeks.

What it does:

Dovobet® gel contains two medicines in one product; calcipotriol (a vitamin D-like substance) and betamethasone (a corticosteroid) that work together to control psoriasis.

Psoriasis lesions are areas of inflamed skin where the production of skin cells is too rapid. This creates red, scaly, thick patches (plaques) of skin. Treatment is targeted at reducing signs of redness and scaling and symptoms such as itching.

Calcipotriol helps to bring the rate of skin cell growth back to normal. Betamethasone works to reduce inflammation (redness, swelling and itching).

When it should not be used:**Do not use Dovobet® gel:**

- if you are allergic to any of the ingredients or the container of Dovobet® gel
- if you have problems with high calcium levels in your body
- if you have skin infections caused by viruses (e.g. cold sores, chicken pox), a fungus (e.g. athlete's foot, ringworm), bacteria, parasites (e.g. scabies), tuberculosis or syphilis
- on skin areas with perioral dermatitis (red mouth rash), ichthyosis (dry, scaly skin), acne (pimples), rosacea (flushed facial skin),
- on skin areas that have ulcers, open sores, thin skin, easily damaged veins, stretch marks
- to treat other types of psoriasis
- if you have severe liver disease
- if you have severe kidney disease
- in the eyes or on itchy skin of the genital or anal area.

What the medicinal ingredients are:

Calcipotriol monohydrate and betamethasone dipropionate.

Each gram of gel contains 50 mcg calcipotriol (as monohydrate) and 0.5 mg betamethasone (as dipropionate)

What the nonmedicinal ingredients are:

α -tocopherol, butylhydroxytoluene, hydrogenated castor oil, liquid paraffin and polyoxypropylene stearyl ether.

What the container ingredients are:

polyethylene

What dosage forms it comes in:

Dovobet® gel is an almost clear, colourless to slightly off-white gel. Available in 60 g and 2x60 g bottles or 60 g cartridges (for use with applicator).

WARNINGS AND PRECAUTIONS

BEFORE you use Dovobet® gel talk to your doctor or pharmacist if you:

- have diabetes
- have skin infections
- use other medicines that contain corticosteroids or calcipotriol (Vitamin D).
- are pregnant or planning to get pregnant
- are breast feeding

Dovobet® gel is not recommended in children and adolescents under 18 years of age.

Calcipotriol in Dovobet® gel may increase the risk of developing skin cancer caused by ultraviolet radiation (UVR).

While using Dovobet® gel, you should avoid excessive exposure to natural or artificial sunlight (UVR) such as phototherapy, tanning beds, sunlamps, etc.

Do not use Dovobet® gel on your face, skin folds (e.g. groin, armpit, under the breast or in the creases of the buttocks), genitals or on open sores on the skin. Do not use Dovobet® gel in or near the eyes. Dovobet® gel may cause eye irritation and irritation of facial skin.

Do not bandage, apply a dressing or wrap the treated skin area after applying Dovobet® gel on your body.

If used on the scalp, do not cover your scalp with a shower cap, bandages or dressings after applying Dovobet® gel.

If required, your doctor may recommend a blood test to check your calcium level or the functioning of your adrenal gland.

INTERACTIONS WITH THIS MEDICATION

Before using Dovobet® gel tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including

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those you can buy without a prescription, especially medicines that contain a corticosteroid and/or calcipotriol.

PROPER USE OF THIS MEDICATION

Always use Dovobet® gel exactly as your doctor has told you.

Usual dose:

Apply Dovobet® gel once daily to the affected areas. Treatment on the body may be continued for up to 8 weeks. Treatment on the scalp may be continued for up to 4 weeks. After discontinuing treatment, if your psoriasis flares up again later, you can begin a new treatment cycle.

The maximum daily dose is 15 g per day, or 100 g per week of Dovobet® and/or any other products containing calcipotriol. The total body surface area treated, including scalp and body should not exceed 30%.

Before Applying Dovobet® gel:

- Use only on areas of your skin affected by psoriasis and not on skin that does not have psoriasis.
- If applying to your scalp, you don't need to wash your hair before applying Dovobet® gel.



SHAKE bottle well before use. Remove cap.

Using Dovobet® gel on the body:

Apply a sufficient amount of gel on affected area to cover plaque with an even layer.

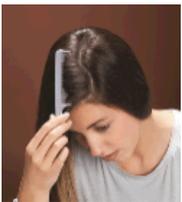


It may help to spread the gel in two perpendicular lines forming a cross within a plaque (i.e. cross unit) to ensure the right amount of drug is applied for the size of the plaque.



Do not spread too thinly. Be sure to apply a sufficient amount of gel to cover the plaque. Massage gently until gel has been absorbed into skin.

Using Dovobet® gel on the scalp:



- Comb dry hair first to remove loose psoriasis scales.
- For long hair, gently part your hair to reveal affected scalp area.

- Squeeze a pea-size drop of Dovobet® gel onto your fingertip.
- Apply gel with your finger to affected scalp areas that have visible psoriasis.
- For a larger area of plaque or for very thick hair, you may need to re-part hair to expose neighbouring psoriasis area. Repeat until the entire affected area (or plaque) is covered with an even layer of gel.

After applying Dovobet® gel:

- Wash your hands well after applying Dovobet® gel.
- It is important to leave treatment areas uncovered. Do not bandage, apply a dressing or wrap the skin or scalp.
- Do not wash your body/hair immediately after application in order to achieve optimal effect. Dovobet® gel should be left on body/scalp until absorbed.
- Dovobet® gel should not be applied 12 hours before or after colouring, perming or any chemical hair treatments. To help avoid irritation, always ask your doctor about using any hair treatments with scalp psoriasis.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

If you forget to use Dovobet® gel use it as soon as you remember. Next time, follow your regular application routine. It's important not to use Dovobet® gel more than once a day.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effect with use of Dovobet® gel on the scalp as well as on the body is itching. Other less common effects reported for Dovobet® gel include: burning sensation of the skin, skin pain or irritation, inflammation of hair root, hair loss, rash (with or without pustules), skin infection, eye irritation, redness, acne, dizziness, dry skin, headache, facial swelling, flushing, migraine, outer ear infection, sinus infection, increased blood calcium level, increased blood parathyroid hormone and decreased blood phosphorus level.

Side effects caused by long term use of corticosteroid-containing products such as Dovobet include: thinning of the skin, stretch marks or surface veins, changes in hair growth, red mouth rash, skin rash with inflammation, small white spots, lightening of skin colour.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist	Stop taking drug and call your doctor or pharmacist
Uncommon: Worsening of psoriasis (red, scaly, thick patches of skin)	✓	
Rare: Pustular psoriasis (red area with yellowish pustules, headache, fever, chills, arthralgia, malaise, anorexia, nausea)		✓
Rare: Adrenal effects (weakness, increased urination/thirst, fatigue, weight loss), cataracts, infections	✓	
Very Rare: Allergic reaction (rash, itching, swelling, trouble breathing, dizziness)		✓
Very Rare: High blood calcium (fatigue, depression, mental confusion, anorexia, nausea, vomiting, constipation, increased urination/thirst)		✓

This is not a complete list of side effects. For any unexpected effects while taking Dovobet® gel, contact your doctor or pharmacist.

HOW TO STORE IT

Store at 15-30 °C. Do not refrigerate. Protect from light by keeping the bottle in the carton between applications.

- Keep Dovobet® gel out of the reach and sight of children and pets.
- Use the medicine within 6 months of first opening the bottle.
- Do not use Dovobet® gel after the expiry date on the label (EXP).

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701D
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: www.leo-pharma.ca or by contacting the sponsor, LEO Pharma Inc., at: 1-800-668-7234.

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