

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

This leaflet is part III of a three-part "Product Monograph" published when DOVOBET 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. Contact your doctor or pharmacist if you have any questions about this drug.

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

DOVOBET should be used topically for up to 4 weeks to treat psoriasis plaques on your body.

DOVOBET should not be used on the face.

What it does:

DOVOBET ointment contains two medicines in one product; calcipotriol (a vitamin D-like substance) and betamethasone dipropionate (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 dipropionate works to reduce inflammation (redness, swelling and itching).

When it should not be used:**Do not use DOVOBET ointment:**

- if you are allergic to any of the ingredients in DOVOBET ointment, or to components of the tube
- 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
- in the eyes

What the medicinal ingredients are:

Calcipotriol and betamethasone dipropionate

What the important nonmedicinal ingredients are:

α -tocopherol, butylhydroxytoluene, white soft paraffin, liquid paraffin, polyoxypropylene stearyl ether.

What the container ingredients are:

Aluminium lacquered with epoxyphenol, polyethylene.

What dosage forms it comes in:

DOVOBET is available as a topical ointment containing 50 mcg/g calcipotriol (as monohydrate) and 0.5 mg/g betamethasone (as dipropionate). Available in 30 g, 60 g, and 120 g lacquered aluminium tubes (equipped with an aluminium membrane) with re-closable polyethylene screw cap.

WARNINGS AND PRECAUTIONS

BEFORE you use DOVOBET ointment 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 ointment is not recommended in children and adolescents under 18 years of age.

Calcipotriol in DOVOBET ointment may increase the risk of developing skin cancer caused by ultraviolet radiation (UVR).

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

Do not use DOVOBET ointment 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 ointment in or near the eyes. DOVOBET ointment may cause eye irritation and irritation of facial skin.

Do not bandage, apply a dressing or wrap the treated skin area after applying DOVOBET ointment on your body.

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 ointment tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those you can buy without a prescription, especially medicines that contain a corticosteroid and/or calcipotriol.

PROPER USE OF THIS MEDICATION

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Usual dose:

DOVOBET should be gently rubbed onto affected skin areas once a day for up to 4 weeks. 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 should not exceed 30%.

Using the ointment:

- Remove the cap. Check that the aluminium seal has not been broken before you use it for the first time. To break the seal, use the other end of the cap to pierce the seal.
- Gently rub the ointment on the areas of your skin affected by psoriasis. Wash your hands after using DOVOBET to prevent getting any on your face. No special dressing or cover is needed.
- If you accidentally spread DOVOBET onto surrounding healthy skin, wash it off right away.
- DOVOBET is not recommended for use on your face. If you accidentally get some on your face, wash it off right away.
- Do not apply DOVOBET on large areas of damaged skin, in skin folds or under an air tight bandage/dressing. This could increase your risk of side effects.
- If DOVOBET ointment is used together with DOVONEX® cream, ointment or scalp solution, then the combined total for all products together should not be greater than 15 g per day or 100 g per week.

For example, if you use 60 g of DOVOBET ointment in a week, you should not use more than 40 mL of DOVONEX scalp solution during the same week.

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 at the right time, use it as soon as you remember. Then go on as before.

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
	Only if severe	In all cases	
Uncommon: worsening of psoriasis (red, scaly, thick patches of skin)			√
Rare: pustular psoriasis (headache, fever, chills, arthralgia, malaise, anorexia, nausea)			√
Rare: adrenal effects (weakness, increased urination/thirst, fatigue, weight loss)		√	
Rare: skin thinning (visible veins, stretch marks)	√		
Very rare: allergic reaction (rash, itching, swelling, trouble breathing, dizziness)			√
Very rare: high blood calcium levels (fatigue, depression mental confusion, anorexia, nausea, vomiting, constipation, increased urination and in some patients, cardiac arrhythmias)			√

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

HOW TO STORE IT

Store at 5 to 25°C. Use within 12 months of first opening the tube.

- For easy spreading do not refrigerate the ointment.
- Keep DOVOBET in a safe place where children cannot reach it.
- Keep DOVOBET away from your pets. The medicine (calcipotriol) can be fatal to dogs if eaten. If your dog eats DOVOBET contact a veterinarian immediately.
- Do not use DOVOBET past the expiry date marked on the bottom of the tube.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effect from the use of DOVOBET is itching which is usually mild.

Other side effects of using DOVOBET may include:

- local irritation
- burning and stinging sensation
- dryness
- various types of skin rashes/dermatitis
- photosensitivity and hypersensitivity reactions
- red and swollen hair follicles
- lightening of skin colour
- facial rash and swelling

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 1-866-234-2345
By toll-free fax: 1-866-678-6789
Online: www.healthcanada.gc.ca/medeffect
By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:
Canada Vigilance National Office
Marketed Health Products Safety and Effectiveness
Information Bureau Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

NOTE: If you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. 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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