

PACKAGE LEAFLET

Package leaflet: Information for the user

Dotevatrol 50 microgram/g + 0.5 mg/g Ointment

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 or pharmacist or nurse.
- This medicine has been prescribed for you only. 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.

What is in this leaflet

1. What Dotevatrol Ointment is and what it is used for
2. What you need to know before you use Dotevatrol Ointment
3. How to use Dotevatrol Ointment
4. Possible side effects
5. How to store Dotevatrol Ointment
6. Contents of the pack and other information

1. What Dotevatrol Ointment is and what it is used for

Dotevatrol 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. Dotevatrol 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. What you need to know before you use Dotevatrol Ointment

Do not use Dotevatrol Ointment:

- If you are allergic to calcipotriol, betamethasone or any of the other ingredients of this medicine (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 Dotevatrol Ointment 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).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Dotevatrol Ointment

- if you are using other medicines that contain corticosteroids, as you may get side effects
- if you use 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)
- if you have diabetes mellitus (diabetes), as your blood sugar/glucose level may be affected by the steroid
- if your skin becomes infected, as you may need to stop your treatment
- if you have a certain type of psoriasis called guttate psoriasis
- if 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 and adolescents

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

Other medicines and Dotevatrol Ointment

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. If your doctor has agreed that you can breast-feed, take care and do not apply Dotevatrol Ointment to the breast area.

Driving and using machines

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

Dotevatrol 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 Dotevatrol Ointment

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How to put on Dotevatrol Ointment: 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 Dotevatrol Ointment (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 Dotevatrol 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 Dotevatrol Ointment?

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

If you have used more Dotevatrol Ointment than you should

Contact your doctor if you have used more than 15 grams in one day. Excessive prolonged use of Dotevatrol Ointment 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 Dotevatrol Ointment

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

If you stop using Dotevatrol Ointment

The use of Dotevatrol Ointment 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, this medicine 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 reported for Dotevatrol Ointment:

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.

Rare (may affect up to 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 using Dotevatrol Ointment and tell your doctor as soon as possible.

Serious side effects reported for the components of Dotevatrol Ointment:

Calcipotriol

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 Dotevatrol Ointment, 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.

Betamethasone

Some serious side effects are known to be caused by betamethasone (a strong steroid), one of the ingredients in Dotevatrol Ointment. 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.

Less serious side effects reported for Dotevatrol Ointment

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

Common side effects (may affect up to 1 in 10 people)

- Itching
- Rash
- Burning sensation.

Uncommon (may affect up to 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 cannot be estimated from the available data

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

Less serious side effects reported for the components of Dotevatrol Ointment

Calcipotriol

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 has also been reported
- Eczema.

If you notice the above or any other changes in your health while taking this medicine, tell your doctor.

Betamethasone

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).

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.

5. How to store Dotevatrol Ointment

- Keep this medicine out of the sight and reach of children.
- Do not use Dotevatrol Ointment 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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dotevatrol Ointment contains

The active substances are:
Calcipotriol and betamethasone.

One gram of ointment contains 50 micrograms of calcipotriol (anhydrous) and 0.5 mg of betamethasone (as 0.643 mg betamethasone dipropionate).

The other ingredients are:

- liquid paraffin
- polyoxypropylene-15-stearyl ether
- white soft paraffin
- butylhydroxytoluene (E321).

What Dotevatrol Ointment looks like and contents of the pack

Dotevatrol Ointment is an off-white to yellow coloured ointment filled in aluminium tubes with polyethylene closures.

Pack sizes: 30, 60 and 120 g.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Teva Pharma B.V.
Computerweg 10
3542 DR Utrecht
The Netherlands

Manufacturer

Teva Pharma B.V., Swensweg 5, 2031 GA Haarlem, The Netherlands.

Merckle GmbH, Ludwig-Merckle-Straße 3, 89143 Blaubeuren, Germany.

Teva Operations Poland Sp. z.o.o., ul. Mogilska 80. 31-546, Krakow, Poland.

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

Belgium	Calcipotriol /Betamethason Teva 50 mcg/g + 0,5 mg/g zalf
Denmark	Calcipotriol/Betamethasone Teva
Finland	Calcipotriol/Betamethasone ratiopharm 50/ 500 mikrog/g voide
France	Calcipotriol/Bétaméthasone TEVA 50 microgrammes/0,5 mg/g, pommade
Germany	Calcipotriol/Betamethason-AbZ 50 Mikrogramm/g + 0,5 mg/g Salbe
Ireland	Dotevatrol 50 microgramgs/g + 0.5 mg/g Ointment
Iceland	Calcipotriol/Betamethasone ratiopharm 50 microg/g + 0,5 mg/g, smyrslí
Italy	Calcipotriolo e Betametasone Teva
Netherlands	Calcipotriol/Bethamethason Teva 50 microgram/g + 0,5 mg/g, zalf
Norway	Calcipotriol/Betamethasone Teva
Poland	Calcipotriol + Betamethasone Teva
Portugal	Betametasona + Calcipotriol ratiopharm
Spain	Calcipotriol/Betametasona Teva 50 microgramos/g + 0,5 mg/g pomada
Sweden	Calcipotriol/Betamethasone Teva 50 mikrogram/g + 0,5 mg/g salva
Slovenia	Psipot 50 mikrogramov/500 mikrogramov v 1 g mazilo
United Kingdom	Dalbecal 50 microgram/g + 0.5mg/g ointment

This leaflet was last approved in October 2013