

PACKAGE LEAFLET: INFORMATION FOR THE USER

Dovobet 50 microgram/0.5 mg/g gel

calcipotriol/betamethasone

Read the entire 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.
- Do you have any further questions? Please ask your doctor or pharmacist.
- Do not pass this medicine on to others. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

1. What is Dovobet and what is this medicine used for?
2. When should you not use this medicine or be extra careful with it?
3. How do you use this medicine?
4. Possible side effects
5. How do you store this medicine?
6. Contents of the package and other information

1. WHAT IS DOVOBET AND WHAT IS THIS MEDICINE USED FOR?

This medicine is used for the topical treatment of scalp psoriasis in adults and for the treatment of mild to moderate plaque psoriasis (psoriasis vulgaris) on other parts of the body in adults. Psoriasis is caused by your skin cells being produced too quickly. This causes redness, scaling, and thickening of the skin.

This medicine contains calcipotriol and betamethasone. Calcipotriol helps to normalize the growth rate of skin cells and betamethasone acts as an anti-inflammatory.

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAREFUL WITH IT?

When should you not use this medicine?

- You are allergic to any of the substances in this medicine. You can find these substances in section 6.
- if you have problems with the calcium levels in your body (consult your doctor)
- if you have certain forms of psoriasis such as psoriasis erythroderma, exfoliative psoriasis and psoriasis pustulosa (consult your doctor).

This medicine contains a potent corticosteroid (adrenal cortex hormone), therefore DO NOT use it on skin affected by:

- skin infections caused by viruses (for example herpes or chickenpox)
- skin infections caused by fungi (for example athlete's foot or ringworm)
- skin infections caused by bacteria
- skin infections caused by parasites (e.g., scabies)

- tuberculosis (TB)
- peri-oral dermatitis (red rash around the mouth)
- thin skin, fragile veins, stretch marks
- ichthyosis (dry skin with fish scales)
- acne (acne)
- rosacea (severe flushing or redness of the facial skin)
- ulcers or skin wounds.

When should you be extra careful with this medicine?

Contact your doctor, nurse, or pharmacist before using this medicine and during use when:

- you are using other medicines that contain corticosteroids because you may experience side effects from them
- you have used this medicine for a long time and plan to stop using it (because there is a risk that psoriasis may worsen or return when steroids are suddenly stopped)
- you have diabetes mellitus (diabetes) because your blood sugar/glucose level may be affected by the steroid
- a skin infection occurs, as it may be necessary to stop the treatment
- you have a certain form of psoriasis called psoriasis guttata
- you experience blurred vision or other vision problems.

Special warnings

- Avoid using on more than 30% of your body and do not use more than 15 grams per day
- Avoid using under a bathing cap, bandages, or dressings as this increases the absorption of the steroid promotes
- Avoid using on large affected areas, on mucous membranes, or in skin folds (groin, armpits, under the breasts) as this increases the absorption of the steroid promotes.
- Avoid using on the face or genitals (sexual organs) as these are very sensitive to steroids
- Avoid excessive exposure to the sun, excessive use of tanning beds, or other forms of light therapy.

Children

This medicine is not recommended for use in children under 18 years of age.

Are you using any other medicines?

Are you using in addition to Dovobet other medicines, have you done that recently or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor before using this medicine. If your doctor has agreed that you can breastfeed, be careful and do not apply this medicine to the breasts.

Driving and using machines

This medicine has no effect on the ability to drive and use machines.

Dovobet contains butylhydroxytoluene (E321)

Dovobet contains butylhydroxytoluene (E321). This can cause local skin reactions (e.g., contact dermatitis) or irritation to the eyes and mucous membranes.

3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Where to apply this medicine: use on the skin (cutaneous).

Instructions for correct use

- Use only on the psoriasis patches and not on other parts of the skin that are not affected by psoriasis.
- Shake the bottle before use and remove the cap.
- Press a little gel onto a clean finger or directly onto the psoriasis spot.
- Apply this medication to the affected skin with your fingertips and gently rub it in until the psoriasis spot is completely covered with a thin layer of gel.
- Do not bandage, tightly cover, or wrap the treated area.
- Wash your hands carefully after applying this medication. This prevents the gel from accidentally getting on other body parts (especially the face, mouth, and eyes).
- You do not need to worry if a little gel accidentally gets on the unaffected skin next to the psoriasis spots, but wipe it off if the gel spreads too far.
- To achieve optimal effect, it is recommended not to bathe or shower immediately after applying this medication.
- Avoid contact with materials sensitive to grease stains (e.g., silk) after applying the gel.

If you have psoriasis on the scalp

- Before applying this medication to the scalp, you should first comb your hair to remove any loose flakes. Tilt your head to ensure that this medication does not run onto your face. It is easier if you create a drug medication with your fingertips to the affected area and gently rub the gel in.

It is not necessary to wash your hair before applying this medication.

1. Shake the bottle for use
2. Apply a drop of this product to your fingertip
3. Apply to the areas of your scalp where you feel the raised psoriasis patch and rub the gel into the skin. Depending on the size of the affected area, 1-4 g (about a teaspoon) is usually sufficient.

To achieve an optimal effect, it is recommended not to wash the hair immediately after applying this product. Let this product work during the day or night. When you wash your hair after applying the gel, you can consider the following instructions:

4. Apply a mild shampoo to the dry hair, especially on the areas where the gel was applied.
5. Let the shampoo work on the scalp for a few minutes before rinsing it out.
6. Wash your hair as usual.

If necessary, you can repeat steps 4-6 once or twice.

Duration of the treatment

- Use the gel once a day. It may be more pleasant to use the gel in the evening
- The usual initial treatment period is 4 weeks for treatment of the scalp and 8 weeks for treatment of psoriasis elsewhere on the body.
- Your doctor may decide to change the treatment period
- Your doctor may decide on a follow-up treatment
- Do not use more than 15 g per day

If you are also using other products containing calcipotriol, the total use of products containing calcipotriol should not exceed 15 grams per day. The area being treated should not be larger than 30% of the total body surface.

What can I expect when using this medicine?

Most patients see a clear result after 2 weeks, even if the psoriasis is not yet gone at that time.

Have you used too much of this medicine?

Consult your doctor if you have used more than 15 grams per day.

Excessive use of this medicine can also cause problems with the calcium in your blood, which usually normalizes when the treatment is stopped.

It may be necessary for your doctor to perform a blood test to check if the use of too much gel has caused any problems with the calcium in your blood.

Excessive prolonged use can also cause your adrenal glands to stop working properly (the adrenal glands are located near the kidneys and they produce hormones).

Did you forget to use this medicine?

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

If you stop using this medicine

The use of this medicine must be stopped on the advice of your doctor. You may need to gradually stop using this medicine, especially if you have used it for a long period.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like any medicine, this medicine can have side effects, although not everyone gets them.

Serious side effects

Contact your doctor or nurse immediately or as soon as possible if any of the following side effects occur. It may be necessary to stop the treatment. The following serious side

effects have been reported for this medicine Sometimes (occur in less than 1 in 100 users):

- Worsening of psoriasis. Inform your doctor immediately if the psoriasis worsens.

Some serious side effects are caused by betamethasone (a potent active steroid), and one of the components of this medicine. You must inform your doctor as soon as possible if any of these serious side effects occur. These side effects mainly occur after prolonged use, with use in skin folds (groin, armpits, under the breasts), with use under occlusive dressings, or with use on large skin surfaces.

It concerns the following side effects:

- Adrenal gland dysfunction. Symptoms include fatigue, depression, and anxiety.
- Cataracts (symptoms include blurred vision, night blindness, and sensitivity to light) or increased pressure in the eye (symptoms include eye pain, red eye, reduced or blurred vision).
- Infections (because the immune system that fights infections is suppressed or weakened).
- Pustular psoriasis (red skin surface with yellowish pustules, usually occurs on hands or feet). If you notice this side effect, stop using this medicine and inform your doctor as soon as possible.
- Effect on the control of diabetes mellitus (if you have diabetes, you may experience fluctuations in your blood sugar levels).

Serious side effects caused by calcipotriol

- Allergic reactions with noticeable swelling of the face or other parts of the body such as the hands or feet. Swelling of the mouth/throat and breathing difficulties may occur. If you have an allergic reaction, stop using this medicine, inform your doctor immediately or go to the emergency department of the nearest hospital.
- During treatment with this gel, the calcium level in your blood or urine may increase (usually if too much gel was used). Symptoms of increased calcium levels include excessive urination, constipation, muscle weakness, confusion, and coma. This can be serious and you should inform your doctor immediately. When the treatment is stopped the calcium level normalizes ..

severe serious side effects

The following less serious side effects have been reported for this medication. Common (occur in less than 1 in 10 users):Itching

- ..

users):Irritation

- of the eyes Burning
- sensation of the skin skin
- Irritated or painful skin
- Inflammation or swelling of the hair follicles (folliculitis)
- Rash with skin inflammation (dermatitis)
- Redness of the skin caused by vasodilation (erythema)
- Acne (pimples)
- Dry skin
- Rash
- Pustular rash
- Skin infection.

Rare (occur in less than 1 in 1000 users):

- Allergic reactions
- Skin striae (striae)
- Skin peeling
- Worsening of psoriasis after stopping treatment (rebound effect).

Unknown (cannot be determined from the available data)

- Temporary discoloration of white or gray hair to a yellowish color at the site of application when the product is used on the scalp.
- Blurred vision

Less serious side effects mainly caused by prolonged use of betamethasone are the following. Inform your doctor or nurse as soon as possible if these occur.

- Thinning of the skin of the skin
- Appearance of dilated blood vessels or stretch marks
- Change in the hair growth
- Red rash around the mouth (peri-oral dermatitis)
- Skin rash with inflammation or swelling (allergic contact dermatitis)
- Golden gel-filled bumps (colloid milia)
- Inflammation or swelling of the hair follicle (folliculitis).
- Less serious side effects caused by

calcipotriol are the following. Dry

- skin Sensitivity of the skin to light, resulting in a rash.
- Sensitivity of the skin to light, resulting in a rash.
- Eczema
- Itching
- Skin irritation
- Burning and stinging sensation
- Redness of the skin due to dilation of small blood vessels (erythema)
- Rash
- Rash with inflammation of the skin (dermatitis)
- Worsening of psoriasis.

Reporting of side effects side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre , www.lareb.nl www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

- Keep out of the sight and reach of children.
- Do not use this medicine after the expiry date. It can be found on the bottle after EXP. It includes a month and a year. The last day of that month is the expiry date.
- Do not store in the refrigerator. Keep the bottle in the outer packaging to protect from light.
- The bottle must be discarded 6 months after first opening.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. CONTENTS OF THE PACKAGE AND OTHER INFORMATION

What substances are in this medicine?

The active substances in this medicine are: calcipotriol and betamethasone.

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

The other substances in this medicine are:

- liquid paraffin
- polyoxypropylene stearyl ether
- hydrogenated castor oil
- butylated hydroxytoluene (E321)
- all-rac- α -..

Dovobet Dovobet what does it look like and how much is in a package?

Dovobet is a nearly transparent, colorless to slightly cream-colored gel in high-density polyethylene bottles with a low-density polyethylene nozzle and a high-density polyethylene screw cap. The bottles are in a cardboard package.

Package sizes: 15 g, 30 g, 60 g, 80 g, 2 x 60 g, 2 x 80 g, and 3 x 60 g.

Not all mentioned package sizes are marketed.

Marketing authorization holder and manufacturer

The marketing authorization holder is:

LEO Pharma A/S
Industriparken 55
DK-2750 Ballerup
Denmark.

The manufacturers are:

LEO Pharma A/S
Industriparken 55
DK-2750 Ballerup
Denmark

LEO Laboratories Ltd. (LEO Pharma)
285 Cashel Road
Dublin 12
Ireland.

For more information about this medicine, you can contact the local representative of the marketing authorization holder.

LEO Pharma B.V.
Delflandlaan 1

1062EA Amsterdam
Tel: (020) 510 41 41
Fax: (020) 510 41 42
e-mail: leo-pharma.nl@leo-pharma.com

Marketing authorization number: RVG 100401

This medicine is registered in EEA member states under the following names:

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

Dovobet[®]: Belgium, Cyprus, Greece, Ireland, Italy, Luxembourg, Netherlands, United Kingdom

This leaflet was last approved in August 2022.

Detailed information about this medicine is available on the website of the Medicines Evaluation Board.

LEAFLET: INFORMATION FOR THE USER

Dovobet 50 micrograms/0.5 mg/g gel

calcipotriol/betamethasone

Applicator

Read the entire 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.

Do you have any questions? Please contact your doctor or pharmacist.

Do not pass this medicine on to others, as it is prescribed only for you. It may be harmful to others, even if they have the same symptoms as you.

Do you experience any of the side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet

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2. When should you not use this medicine or be extra careful with it?
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5. How do you store this medicine?
6. Contents of the package and other information

1. WHAT IS DOVOBET AND WHAT IS THIS MEDICINE USED FOR?

This medicine is used for the topical treatment of scalp psoriasis in adults and for the treatment of mild to moderate plaque psoriasis (psoriasis vulgaris) on other parts of the body in adults. Psoriasis is caused by your skin cells being produced too quickly. This causes redness, scaling, and thickening of the skin.

This medicine contains calcipotriol and betamethasone. Calcipotriol helps to normalize the growth rate of skin cells and betamethasone acts as an anti-inflammatory.

2. WHEN SHOULD YOU NOT USE THIS MEDICINE OR BE EXTRA CAUTIOUS?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

if you have problems with the calcium levels in your body (consult your doctor)

if you have certain types of psoriasis such as psoriasis erythroderma, exfoliative psoriasis and psoriasis pustulosa (consult your doctor).

This medicine contains a potent corticosteroid (adrenal cortex hormone), therefore DO NOT use it on skin affected by:

- skin infections caused by viruses (e.g., herpes or chickenpox)
- skin infections caused by fungi (e.g., athlete's foot or ringworm)
- skin infections caused by bacteria
- skin infections caused by parasites (e.g., scabies)
- tuberculosis (TB)
- peri-oral dermatitis (red rash around the mouth)
- thin skin, fragile veins, stretch marks
- ichthyosis (dry skin with fish scales)
- acne (pimples)
- rosacea (severe blushing or redness of the facial skin)
- ulcers or skin wounds.

When should you be extra careful with this medicine?

Contact your doctor or nurse or pharmacist before using this medicine and during use when:

- you use other medicines that contain adrenal cortex hormones (corticosteroids) because you may experience side effects from them
- you have used this medicine for a long time and plan to stop using it (because there is a risk that psoriasis may worsen or return when steroid use is suddenly stopped)
- you have diabetes mellitus (diabetes) because your blood sugar/glucose level may be affected by the steroid
- if a skin infection occurs, because it may be necessary to stop the treatment
- if you have a certain form of psoriasis called psoriasis guttata
- you experience blurred vision or other vision problems.

Special warnings

- Avoid using on more than 30% of your body and do not use more than 15 grams per day
- Avoid using under a bathing cap, bandages, or dressings as this promotes the absorption of the steroid
- Avoid use on large affected areas, on mucous membranes, or in skin folds (groin, armpits, under the breasts) as this increases the absorption of the steroid
- Avoid use on the face or genitals (sexual organs) as these are very sensitive to steroids
- Avoid excessive exposure to the sun, excessive use of tanning beds or other forms of light therapy.

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Children

This medicine is not recommended for use in children under 18 years of age.

Are you using any other medicines?

Are you using any other medicines besides Dovobet, have you done so recently or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor before using this medicine. If your doctor has agreed that you can breastfeed, be careful and do not apply this medicine to the breasts.

Driving and using machines

This medicine has no effect on the ability to drive and use machines.

Dovobet contains butylhydroxytoluene (E321)

Dovobet contains butylhydroxytoluene (E321). This can cause local skin reactions (e.g., contact dermatitis) or irritation to the eyes and mucous membranes.

3. HOW TO USE THIS MEDICINE?

Always use this medicine exactly as your doctor has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

Where this medicine should be applied: use on the skin (cutaneous).

Read the instructions for use of the Dovobet gel Applicator, at the end of this leaflet, carefully.

In the instructions for use, you will find information about assembling, using, cleaning, and storing the Dovobet gel Applicator.

The Dovobet gel Applicator is referred to as 'the Applicator' in the rest of this leaflet.

Instructions for correct use of this medicine

Use only on the psoriasis patches and not on other parts of the skin that are not affected by psoriasis.

Apply this medicine to the affected skin with the Applicator and gently rub it in until the psoriasis patch is completely covered with a thin layer of gel.

Do not bandage, tightly cover, or wrap the treated area.

After applying this medicine, wash your hands carefully if you have gotten gel on your fingers. This prevents the gel from accidentally getting on other parts of the body (especially the face, mouth, and eyes).

You do not need to worry if a little gel accidentally gets on the unaffected skin next to the psoriasis patches, but wipe it off if the gel spreads too far.

To achieve an optimal effect, it is recommended not to bathe or shower immediately after applying this medicine.

Avoid contact with materials sensitive to grease stains (e.g., silk) after applying the gel.

It is not necessary to wash the hair before applying this product the hair.

To achieve an optimal effect, it is recommended not to wash the hair immediately after applying this product. Allow this product to work throughout the day or night. When you wash your hair after applying the gel, you can consider the following instructions:

1. Apply a mild shampoo to the dry hair, especially on the areas where the gel was applied.
2. Let the shampoo work on the scalp for a few minutes before rinsing it out.
3. Wash your hair as usual.

If necessary, you can repeat steps 1-3 once or twice.

Duration of the treatment

Use the gel once a day. It may be more convenient to use the gel in the evening.

The usual initial treatment period is 4 weeks for treating the scalp and 8 weeks for treating psoriasis elsewhere on the body.

Your doctor may decide to change the treatment period.

Your doctor may decide on a follow-up treatment.

Do not use more than 15 g per day. This means you should use one Applicator with 60 grams of gel for at least 4 days.

An amount of 1 g to 4 g per day is usually sufficient for treating the scalp.

If you are also using other products containing calcipotriol, the total use of products containing calcipotriol should not exceed 15 grams per day. The area being treated should not be larger than 30% of the total body surface. One pump delivers 0.05 g of this product.

What can I expect when using this product?

Most patients see a clear result after 2 weeks, even if the psoriasis is not yet gone at that time.

Have you used too much of this product?

Consult your doctor if you have used more than 15 grams per day.

Excessive use of this product can also cause problems with the calcium in your blood, which usually normalizes when the treatment is stopped.

It may be necessary for your doctor to perform a blood test to check if the use of too much gel has caused any problems with the calcium in your blood.

Excessive long-term use can also cause your adrenal glands to not work properly (the adrenal glands are located near the kidneys and they produce hormones).

Have you forgotten to use this product?

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

If you stop using this product

- With the use of this medicine should be stopped on the advice of your doctor. It may be necessary to gradually stop using this medicine, especially if you have used it for a long period.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like any medicine, this medicine can have side effects , although not everyone gets them.

Serious side effects

Contact your doctor or nurse immediately or as soon as possible if any of the following side effects occur. It may be necessary to stop the treatment.

The following serious side effects have been reported for this medicine Sometimes (occur in less than 1 in 100 users):

Worsening of psoriasis. Inform your doctor immediately if the psoriasis worsens.

Some serious side effects are caused by betamethasone (a potent steroid), and one of the components of this medicine. You should inform your doctor as soon as possible if one of these serious side effects occurs. These side effects mainly occur after prolonged use, when used in skin folds (groin, armpits, under the breasts), under occlusive dressings, or on large skin areas.

The following side effects are involved:

Adrenal glands not functioning properly. Symptoms include fatigue, depression, and anxiety.

Cataracts (symptoms are blurred vision, night blindness, and sensitivity to light) or increased pressure in the eye (symptoms are eye pain, red eye, reduced or blurred vision).

Infections (because the immune system that fights infections is suppressed or weakened).

- Pustular psoriasis (red skin surface with yellowish pustules, usually occurs on hands or feet). If you notice this side effect, stop using this medicine and inform your doctor as soon as possible.

Impact on the control of diabetes mellitus (if you have diabetes, you may experience fluctuations in your blood sugar levels).

Serious side effects caused by calcipotriol

Allergic reactions with noticeable swelling of the face or other parts of the body such as the hands or feet. Swelling of the mouth/throat and breathing difficulties may occur. If you have an allergic reaction, stop using this medicine, inform your doctor immediately, or go to the emergency department of the nearest hospital. During treatment with this gel, the calcium level in your blood or urine may increase (usually if too much gel was used). Symptoms of increased calcium levels include excessive urination, constipation, muscle weakness, confusion, and coma. This can be serious, and you should inform your doctor immediately. When the treatment is stopped the calcium level normalizes ..

serious side effects side effects

Common (occur in less than 1 in 10 users):

Itching

..

Irritation

of the of the eyes

Burning sensation of the skin

Irritated or painful skin

Inflammation or swelling of the hair follicles (folliculitis)

Rash with skin inflammation (dermatitis)

Redness of the skin caused by vasodilation (erythema)

Acne (pimples)

skin skin

Skin rash

Pustular skin rash

Skin infection.

Rare (occur in less than 1 in 1000 users):

Allergic reactions

Stretch marks (striae)

Skin peeling

Worsening of psoriasis after stopping treatment (rebound effect).

Not known (cannot be determined from the available data)

Temporary discoloration of white or gray hair to a yellowish color at the application site when the product is used on the scalp.

Blurred vision

Less serious side effects mainly caused by long-term use of betamethasone are the following. Inform your doctor or nurse as soon as possible if these occur.

Thinning of the skin Appearance of dilated blood vessels or stretch marks

Change

- - in hair growth
 - Red rash around the mouth (peri-oraldermatitis) dermatitis)
 - Golden gel-filled bumps (colloid milia)Lightening of the skin (depigmentation)
 - Inflammation or swelling of the hair follicle (folliculitis).
- Less serious side effects caused by calcipotriol are the following

Less serious side effects caused by calcipotriol are 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 dilation of small blood vessels (erythema)
- Rash
- Rash with inflammation of the skin (dermatitis)
- Worsening of psoriasis.

Reporting side effects If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre side effects
If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the cartridge after EXP. It includes a month and a year. The last day of that month is the expiry date.

Do not store in the refrigerator.

The Applicator is disposable. The Applicator must be discarded 6 months after first opening, along with any remaining gel.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What substances are in this medicine?

The active substances in this medicine are: calcipotriol and betamethasone.

One gram of gel contains 50 micrograms of calcipotriol (as monohydrate) en 0,5 mg betamethasone (als dipropionate).

The andliquid

paraffin polyoxypropylene stearyl ether
hydrogenated
castor oil butylated hydroxytoluene
(E321) all-
rac----tocopherol.

What does Dovobet look like and what is in a package?

Dovobet is an almost transparent, colorless to slightly cream-colored gel in a polypropylene filling (with a high-density polyethylene plunger and screw cap). The filling and the head of the Applicator (polypropylene exterior, polyoxymethylene handle and thermoplastic elastomer nozzle) are assembled before first use. The polypropylene protective cap is intended for the storage of the Applicator.

The filling(s), head(s) of the Applicator(s), and protective cap(s) are packed in a box. Package sizes: 60 g (equivalent to 68 ml) and 2 x 60 g (equivalent to 2 x 68 ml)

Not all mentioned package sizes are marketed.

Marketing authorization holder and manufacturer

The authorization holder is:

LEO Pharma A/S
Industriparken 55
DK-2750 Ballerup
Denmark.

The manufacturers are:

LEO Pharma A/S
Industriparken 55
DK-2750 Ballerup
Denmark

LEO Laboratories Ltd. (LEO Pharma)
285 Cashel Road
Dublin 12
Ireland.

The instructions for use of the Applicator can be found at the end of this leaflet.

For more information about this medicine, you can contact the local representative of the marketing authorization holder.

LEO Pharma B.V.
Delflandlaan 1
1062EA Amsterdam
Tel: (020) 510 41 41
Fax: (020) 510 41 42
e-mail: leo-pharma.nl@leo-pharma.com

Marketing authorization number: RVG 100401

- This medicine is registered in EEA member states under the following names:
Daivobet[®]: Bulgaria, Denmark, Germany, Estonia, Finland, France, Hungary, Croatia, Latvia, Lithuania, Norway, Austria, Poland, Portugal, Romania, Slovenia, Slovakia, Spain, Czech Republic, Iceland, Sweden
Dovobet[®]: Belgium, Cyprus, Greece, Ireland, Italy, Luxembourg, Netherlands, United Kingdom

This leaflet was last approved in August 2022.

Detailed information about this medicine is available on the website of the Medicines Evaluation Board.

Transtoyou

Instructions for use Dovobet gel Applicator

Read the leaflet and these instructions for use carefully before use, even if you have previously used Dovobet gel.

The Dovobet gel Applicator is designed to apply Dovobet gel to your skin and/or scalp affected by psoriasis. By using the Dovobet gel Applicator, you can apply Dovobet gel without getting gel on your fingers.

Follow your doctor's instructions regarding your psoriasis treatment.

Do not share the Dovobet gel Applicator with others.

Keep this medicine out of the sight and reach of children.

Your Dovobet gel Applicator consists of the following parts

Preparing your Dovobet gel Applicator

A) Check the expiration date on the cartridge Check the expiration date on the label of the cartridge.

Do not use if expired.

The expiration date on the cartridge refers to the last day of that month. Write the date you assembled the Applicator on the label of the cartridge.

Do not use the Applicator more than 6 months after this date.

B) Remove the screw cap from the cartridge Hold the cartridge upright, turn the cap counterclockwise to open.

Avoid tilting the cartridge to prevent spilling the gel.

Discard the screw cap.

C) Attach the head of the Applicator firmly Hold the cartridge upright and place the head of the

Applicator straight on. Turn the head of the

Applicator clockwise until the head of the Applicator is securely fastened ..

You will hear a clicking sound when it is securely sealed.

Note:

After this step, it is no longer possible to

the take the Applicator apart. Attempting to do so may break the Applicator.

D) Preparing for first use Make preparations for first use

prepare: ensure that the head of the Applicator and the cartridge are properly assembled.

Gently press the center of the plunger while squeezing the handle until you see gel at the nozzle.

If you are traveling by plane and taking your assembled

Dovobet Dovobet gel Applicator with you, it may be necessary to pump the handle several times after landing before the gel comes out of the nozzle.

Dovobet apply gel to the affected skin

)A Aapply to the affected skin

Hold the nozzle of the Applicator close to your skin and press the handle one or more times, depending on the amount you need. Release the handle completely between each pump. This prevents too little gel from coming out.

One pump delivers 0.05 g Dovobet gel.

F) Use of the spreading surfaces

If you wish, you can use the various spreading surfaces to Dovobet gel gently into the skin.

Be careful not to press the handle while spreading.

G) Application on the scalp and hairline

For applying Dovobet gel on the scalp, you should comb the hair to remove any loose flakes. Tilt your head to prevent Dovobet gel from running into your face. It may help to part your hair before applying Dovobet gel. Locate the area to be treated with your fingers and spread your hair.

Place the nozzle directly on the scalp, apply the gel, and massage the Dovobet gel into the skin.

H) After application

Check that all affected areas are covered.

If necessary, ask someone to help you apply Dovobet gel to areas you cannot reach or see.

Wash hands after use, if you, or someone helping you, got Dovobet gel on your fingers. This prevents accidental spreading of the gel to other parts of the body (especially the face, mouth, and eyes).

After use

I) Clean your Dovobet gel Applicator after each use

Wipe the head of the Applicator clean with a clean, dry tissue after use. Do not squeeze the handle while cleaning.

Note:

Do not clean the Applicator with water, detergent, or other substances.

Do not use damp or wet materials to wipe the Applicator clean.

J) Close the Applicator

After each use, place the protective cap on the Applicator to keep the head of the Applicator clean.

Always check if the protective cap clicks into place to prevent Dovobet gel from leaking during storage and transport.

K) Estimate the amount of remaining Dovobet gel

To estimate the amount of remaining Dovobet gel, look at the position of the plunger at the bottom of the cartridge. The plunger moves up as the gel is used.

Before using again

L) Check the expiration date

Always check the expiration date on the cartridge label before use. Do not use if the expiration date has passed or 6 months after opening the cartridge.

The expiration date on the cartridge refers to the last day of that month.

M) Remove the protective cap

Remove the protective cap by pressing the tab at the back upwards.

Storage

Always ensure the protective cap clicks into place to prevent Dovobet gel from leaking during storage and transport.

See more information on storage in section 5, "How to store this medicine".

Disposal

See the disposal information in section 5, "How to store this medicine".

Transtoyou