

Dovobet® Gel

(calcipotriol/betamethasone dipropionate)

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 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. See Section 4.

This medicine is available using the above name 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 vulgaris) 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 this medicine (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.

Warnings and precautions

Talk to your doctor/nurse/pharmacist before and during use of 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
- you experience blurred vision or other visual disturbances.

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 breasts) 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

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

Pregnancy and breast-feeding

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

Driving and using machines

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

Dovobet contains butylated hydroxytoluene (E321)

Dovobet contains butylated hydroxytoluene (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 this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How to put on Dovobet: Cutaneous use.

Instructions for proper use

- 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 gel
- After applying the gel, avoid contact with textiles which are easily stained by grease (e.g. silk).

If you have scalp psoriasis

- 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.

Washing your hair before application of Dovobet is not necessary.



Shake bottle before use.



Apply a drop of Dovobet to fingertip.



Apply directly to scalp areas where you can feel the raised plaque and rub the Dovobet gel on to the skin.

Depending on the affected area 1-4 g (up to 1 teaspoon) is normally enough.

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. When washing hair after application the following instructions might be useful:



Apply a mild shampoo to the dry hair, especially to those areas where the gel was applied.



Leave the shampoo on the scalp for a couple of minutes before washing.



Wash your hair as usual.

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

Duration of treatment

- 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 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 Dovobet?

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

If you use more Dovobet than you should

Contact your doctor if you have used more than 15 grams 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 a forgotten dose.

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 on 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.

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.

Frequency not known (frequency cannot be estimated from the available data):

- White or grey hair can transiently change to a yellowish colour at the application site when used on the scalp
- Blurred vision.

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 the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the

Google Play or **Apple App Store**. 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 bottle after EXP. The expiry date refers to the last day of that month
- Do not refrigerate. Keep the bottle in the outer carton in order to protect from light.
- 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.
- If the medicines become discoloured or show any other signs of deterioration, consult your pharmacist who will tell you what to do.

6. Contents of the pack and other information

What Dovobet contains

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

The other ingredients are:

liquid paraffin, polyoxypropylene stearyl ether, hydrogenated castor oil, butylhydroxytoluene (E321) and all-rac- α -tocopherol.

What Dovobet looks like and the contents of the pack

An almost clear, colourless to slightly off-white gel filled in high-density polyethylene white colour bottles with a low-density polyethylene nozzle and a high-density polyethylene red colour screw cap. The bottles are placed in cartons.

Pack size: 60 g & 2 x 60 g.

Manufacturer and Product Licence Holder

Manufactured by LEO Laboratories Ltd. (LEO Pharma), 285 Cashel road, Dublin 12, Ireland.

Procured from within the EU by Product Licence holder:

Star Pharmaceuticals Ltd., 5 Sandridge Close, Harrow, Middlesex HA1 1XD. Repackaged by Servipharm Ltd.

POM

PL 20636/2950

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Dovobet is trademark of LEO Pharma A/S.

**Blind or partially sighted?
Is this leaflet hard to see or read?
Call 020 8423 2111 to obtain the
leaflet in a format suitable for you.**

Dovobet® Gel Applicator

(calcipotriol/betamethasone dipropionate)

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 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. See Section 4.

This medicine is available using the above name but will be referred to as Dovobet throughout this leaflet.

What is in this leaflet

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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 vulgaris) 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 this medicine (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.

Warnings and precautions

Talk to your doctor/nurse/pharmacist before and during use of 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
- you experience blurred vision or other visual disturbances.

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 breasts) 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

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

Pregnancy and breast-feeding

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

Driving and using machines

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

Dovobet contains butylated hydroxytoluene (E321)

Dovobet contains butylated hydroxytoluene (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 this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

How to put on Dovobet: Cutaneous use.

Read the Instructions for Use for the Dovobet gel Applicator included at the end of this leaflet carefully before use.

In the Instructions for Use you will find information about assembling, using, cleaning and storing of the Dovobet gel Applicator.

The Dovobet gel Applicator is called 'the Applicator' in the remainder of this leaflet.

Instructions for proper use of Dovobet

- Use only on your psoriasis and do not use on skin which does not have psoriasis
- Apply Dovobet to the affected area with the Applicator, 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 if you get gel on your fingers. 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 gel
- After applying the gel, avoid contact with textiles which are easily stained by grease (e.g. silk).

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.

When washing hair after application the following instructions might be useful:



Apply a mild shampoo to the **dry hair**, especially to those areas where the gel was applied.



Leave the shampoo on the scalp for a couple of minutes before washing.



Wash your hair as usual.

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

Duration of treatment

- 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 15 grams in one day. This means that one 60 g Applicator should last for at least 4 days
- For treatment of the scalp usually an amount between 1 g and 4 g per day is sufficient.

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. One full pump delivers 0.05 g Dovobet gel.

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 use more Dovobet than you should

Contact your doctor if you have used more than 15 grams 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 a forgotten dose.

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 on 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.

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.

Frequency not known (frequency cannot be estimated from the available data):

- White or grey hair can transiently change to a yellowish colour at the application site when used on the scalp
- Blurred vision.

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 the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Dovobet

- Keep this medicine out of the sight and reach of children
- Do not use this medicine after the expiry date, which is stated on the cartridge after EXP. The expiry date refers to the last day of that month
- Do not refrigerate
- The Applicator is disposable. Discard the Applicator with any remaining gel 6 months after first opening.
- If your medicines show any signs of deterioration or discolouration, you should seek the advice of your pharmacist who will tell you what to do.

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 Dovobet contains

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

The other ingredients are:

liquid paraffin, polyoxypropylene-11 stearyl ether, hydrogenated castor oil, butylhydroxytoluene (E321) and all-rac- α -tocopherol.

What Dovobet looks like and contents of the pack

Dovobet is an almost clear, colourless to slightly off-white gel filled in a polypropylene cartridge (with a high-density polyethylene plunger and screw cap). The cartridge and the applicator head (polypropylene outer casing, polyoxymethylene lever and thermoplastic elastomer nozzle) is assembled prior to first use. The polypropylene cover is for storage.

The cartridge(s), applicator head(s) and cover(s) are placed in a carton. Pack sizes: 60 g (equivalent to 68 ml).

Manufacturer and Product Licence Holder

Manufactured by
LEO Laboratories Ltd. (LEO Pharma), 285 Cashel road, Dublin 12, Ireland.
LEO Pharma A/S, Industriparken 55, DK-2750 Ballerup, Denmark.
Procured from within the EU by Product Licence holder:
Star Pharmaceuticals Ltd., 5 Sandridge Close, Harrow, Middlesex HA1 1XD. Repackaged by Servipharm Ltd.

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Leaflet revision and issue date (Ref) 29.10.19[3]

Dovobet is trademark of LEO Pharma A/S.

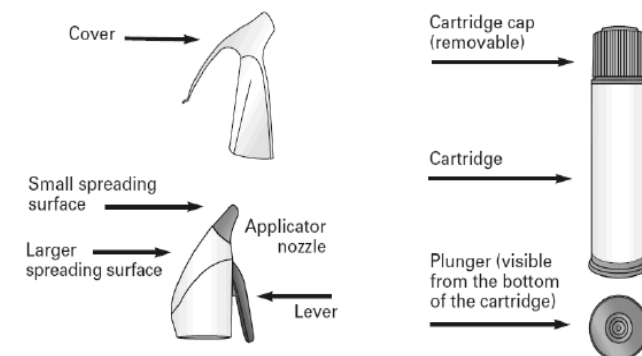
**Blind or partially sighted?
Is this leaflet hard to see or read?
Call 020 8423 2111 to obtain the
leaflet in a format suitable for you.**

Instructions for Use Dovobet® Gel Applicator

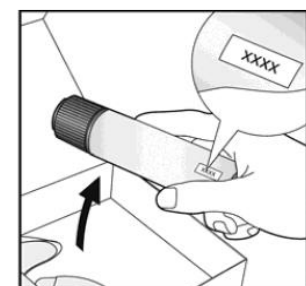
Before use, you should read all of the patient information and the Instructions for Use carefully – even if you have used Dovobet gel before. The Dovobet gel Applicator is designed to apply Dovobet gel to your skin and scalp affected by plaque psoriasis. Using the Dovobet gel Applicator, you can apply Dovobet gel without getting any gel on your fingers. Always follow your doctor's instructions on the treatment of your psoriasis.

Do not share the Dovobet gel or the Applicator with others. Keep this medicine **out of the sight and reach of children**.

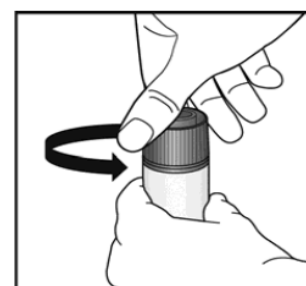
Your Dovobet gel Applicator



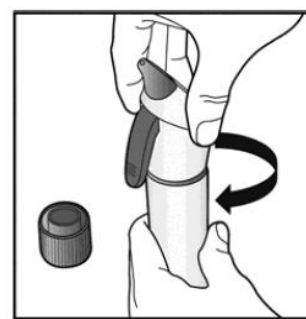
Preparing your Dovobet gel Applicator



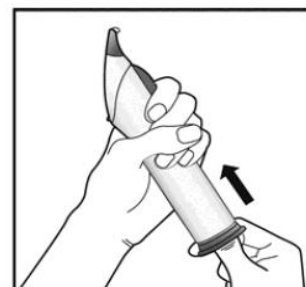
A) Check the expiry date on the cartridge
Check the expiry date on the cartridge label. Do not use if expired. The expiry date on the cartridge refers to the last day of that month. Write the date that you assembled the Applicator on the cartridge label. Do not use the Applicator more than 6 months after this date.



B) Remove the cartridge cap
Holding the cartridge upright, twist the cap anti-clockwise to remove. Avoid tipping the cartridge as this may result in spilling the gel. Discard the cap after removing.



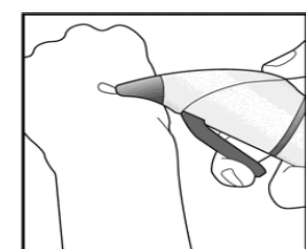
C) Attach applicator head tightly
Keep the cartridge upright and align the applicator head. Screw the applicator head clockwise until the applicator head feels tightly sealed. Clicking sounds will be heard until it is tightly sealed.
Note:
Do not disassemble the Applicator. Attempts to do so may break the Applicator.



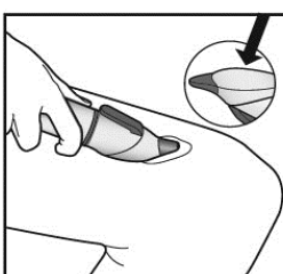
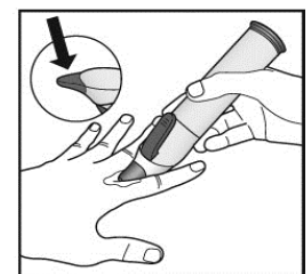
D) Prime before first use
To prime: Make sure that the applicator head and cartridge are tightly assembled.
Gently push up on the centre of the plunger while squeezing the lever until you see gel at the nozzle tip.

If you fly with your assembled Dovobet gel Applicator, you may need to pump the lever a few times to re-prime before applying.

Applying the Dovobet gel to the affected area



E) Apply to the affected area
Place the applicator nozzle close to the affected area and press the lever one or more times to dispense the Dovobet gel. Release the lever fully between each pump to get a full dispense. One full pump delivers 0.05 g Dovobet gel.



F) Use spreading surfaces to massage Dovobet gel across plaques
Use the spreading surfaces to gently massage the Dovobet gel into the affected skin.

Be careful not to press the lever when spreading.

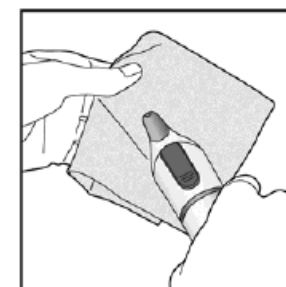


G) To apply to scalp and hairline
Before applying Dovobet to the scalp, comb the hair to remove any loose scales. Tilt your head to make sure Dovobet does not run onto your face. It may help to part your hair before you use Dovobet. Locate the area to treat using your fingers and part your hair. Use the nozzle directly on the scalp to dispense and massage in the Dovobet gel.

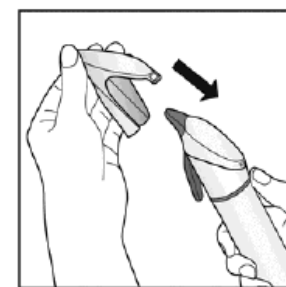
H) After application

Check that the affected areas are sufficiently covered. If needed, ask someone to help you apply the Dovobet gel to areas you cannot reach or see.
Wash hands after use, if you, or someone assisting you, get Dovobet gel on the fingers. This will avoid accidentally spreading the gel to other parts of your body (especially the face, mouth and eyes).

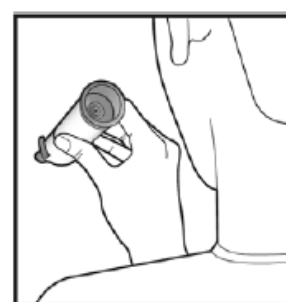
After use



I) Clean your Dovobet gel Applicator after each use
Following use, wipe the applicator head with a clean, dry tissue. Avoid pumping while cleaning.
Note:
• **Do not wash the Applicator with water, detergents or any other substances.**
• **Do not use moist or wet materials to wipe the Applicator.**



J) Cover the Applicator
Replace the cover after each use to keep the applicator head clean. Always ensure the cover is clicked in place to prevent dispensing Dovobet gel during storage and transportation.

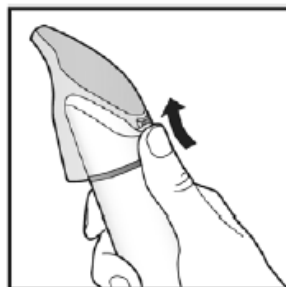


K) Estimate the amount of remaining Dovobet gel
To estimate the amount of remaining Dovobet gel, look in the bottom of the cartridge to see the plunger position. The plunger moves upwards as the gel is used.

Before use again



L) Check expiry date
Always check the expiry date on the cartridge label before use. Do not use if the expiry is exceeded or 6 months after opening the cartridge. The expiry date on the cartridge refers to the last day of that month.



M) Remove cover
Remove the cover by lifting the tab after rear.

Storage
Always ensure the cover is clicked in place to prevent dispensing the gel during storage and transportation. See further information about storage in section 5, 'How to store Dovobet'.

Disposal

See information about disposal in section 5, 'How to store Dovobet'.