

PART III: CONSUMER INFORMATION**PRDOVOBET® Gel
calcipotriol and betamethasone dipropionate gel**

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

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

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

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

What it does:

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

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

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

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

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

What the medicinal ingredients are:

Calcipotriol monohydrate and betamethasone dipropionate.

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

What the nonmedicinal ingredients are:

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

What the container ingredients are:

polyethylene

What dosage forms it comes in:

Dovobet® gel is an almost clear, colourless to slightly off-white gel. Available in 60 g, 80 g and 2x60 g bottles or 60 g cartridges (for use with applicator).

WARNINGS AND PRECAUTIONS

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

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

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

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

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

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

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

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

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

INTERACTIONS WITH THIS MEDICATION

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

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

PROPER USE OF THIS MEDICATION

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

Usual dose:

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

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

Before Applying Dovobet® gel:

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



SHAKE bottle well before use. Remove cap.

Using Dovobet® gel on the body:

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



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



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

Using Dovobet® gel on the scalp:



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

After applying Dovobet® gel:

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

Overdose:

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

Missed Dose:

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

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

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skin rash with inflammation, small white spots, lightening of skin colour.

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

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

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

HOW TO STORE IT

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

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

REPORTING SUSPECTED SIDE EFFECTS

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

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

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

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

MORE INFORMATION

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

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Last revised: September 2018

PART III: CONSUMER INFORMATION

**PRDOVOBET® Gel
with Applicator
calcipotriol and betamethasone dipropionate gel**

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

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

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

What it does:

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

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

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

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

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

What the medicinal ingredients are:

Calcipotriol monohydrate and betamethasone dipropionate. One full pump of the Applicator delivers 0.05g Dovobet® gel containing 2.5 mcg calcipotriol (as monohydrate) and 0.025 mg betamethasone (as dipropionate).

What the nonmedicinal ingredients are:

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

What the container ingredients are:

polypropylene, polyethylene, thermoplastic elastomer

What dosage forms it comes in:

Dovobet® gel is an almost clear, colourless to slightly off-white gel. Available in 60 g, 80 g and 2x60 g bottles or 60 g cartridges (for use with applicator).

WARNINGS AND PRECAUTIONS

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

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- are pregnant or planning to get pregnant
- are breast feeding

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

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

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

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

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

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

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

INTERACTIONS WITH THIS MEDICATION

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Before using Dovobet® gel 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

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

Usual dose:

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

The maximum daily dose is 15 g per day (corresponding to 300 pumps of the applicator), or 100 g per week, in total of all products containing calcipotriol. One full pump delivers 0.05 g Dovobet® gel. The total body surface area treated, including scalp and body should not exceed 30%.

Before Applying Dovobet® gel:

- Assemble your Applicator, see instructions on how to assemble and use the applicator below.
- Use only on areas of your skin affected by psoriasis and not on skin that does not have psoriasis.
- If you accidentally get Dovobet® gel on your face wipe it off.
- If applying to your scalp, you don't need to wash your hair before applying Dovobet® gel.

Using Dovobet® gel on the body:

- Using the Applicator, apply a sufficient amount of gel on affected area to cover plaque with an even layer.



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

- Do not spread too thinly. Be sure to apply a sufficient amount of gel to cover the plaque. Using the spreading surfaces of the Applicator massage gently until gel has been absorbed into skin.

Using Dovobet® gel on the scalp:

- Using the Applicator, apply gel to affected scalp areas that have visible psoriasis.
- For proper use of Dovobet® gel on the scalp see section (g) under Instructions for Assembly and Use of the Applicator.

After applying Dovobet® gel:

- Wash your hands well after contact with Dovobet® gel.
- It is important to leave treatment areas uncovered. Do not bandage, apply a dressing or wrap the skin or scalp.

- Do not wash your body/hair immediately after application in order to achieve optimal effect. Dovobet® gel should be left on body/scalp until absorbed.
- Dovobet® gel should not be applied 12 hours before or after colouring, perming or any chemical hair treatments. To help avoid irritation, always ask your doctor about using any hair treatments with scalp psoriasis.

Overdose:

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

Missed Dose:

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

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

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

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

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
Very Rare: High blood calcium (fatigue, depression, mental confusion, anorexia, nausea, vomiting, constipation, increased urination/thirst)		✓

Please see the instructions for assembly and use of the applicator included at the end of this leaflet.

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Last revised: September 2018

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

HOW TO STORE IT

Store at 15-30 °C. Do not refrigerate.

Keep Dovobet® gel out of the reach and sight of children and pets.

- Use within 6 months of assembly and before the expiry date.

REPORTING SUSPECTED SIDE EFFECTS

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

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

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

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

MORE INFORMATION

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

This leaflet was prepared by LEO Pharma Inc.

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Instructions for Assembly and Use of the Applicator

Before using Dovobet® gel you should read all of the “Consumer Information” carefully - even if you have used Dovobet® gel before.

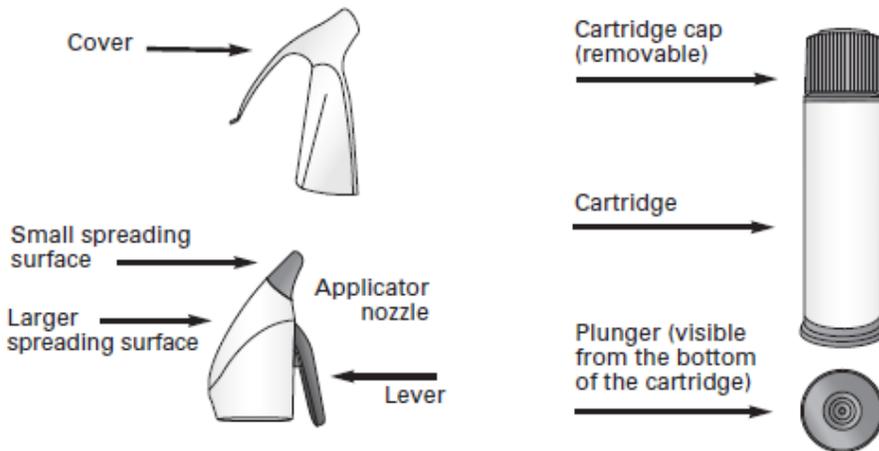
The Dovobet® gel Applicator is designed to apply Dovobet® gel to your scalp and body areas affected by plaque psoriasis (psoriasis vulgaris).

Using the Applicator, you can apply Dovobet® gel without getting any gel on your fingers.

Do not share Dovobet® gel or the Applicator with others.

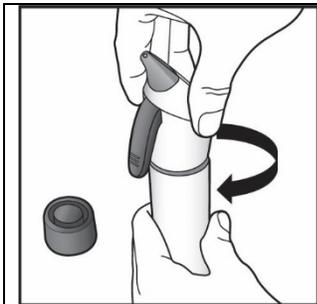
Keep Dovobet® gel out of the reach and sight of children and pets.

Your Dovobet® gel Applicator



Preparing your Applicator

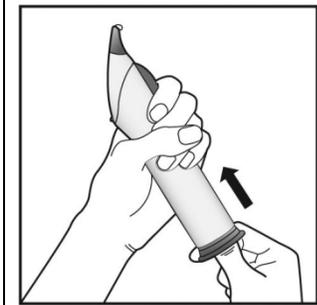
	<p>a. Check the expiry date on the cartridge</p> <p>Check the expiry date on the cartridge label. Do not use if expired. The expiry date refers to the last day of that month. Write the date that you assembled the Applicator on the cartridge label. Do not use the Applicator more than 6 months after this date.</p> <p>Note: Do not assemble the applicator if you do not intend to use the product right away..</p>
	<p>b. Remove the cartridge cap</p> <p>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.</p>



c. Attach the applicator head

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. The Applicator is now correctly assembled.

Note: Do not disassemble the Applicator. Attempts to do so may break the Applicator.

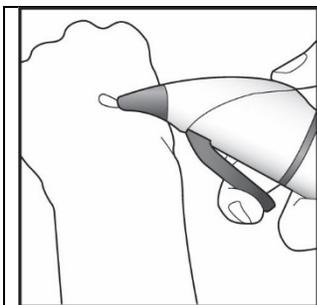


d. Prime before first use

To prime:
Make sure that the applicator head and cartridge are tightly assembled.
Gently push up on the **center** of the plunger while squeezing the lever until you see Dovobet® gel at the nozzle tip.

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

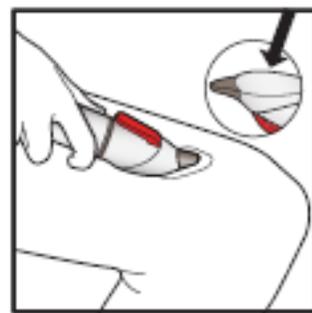
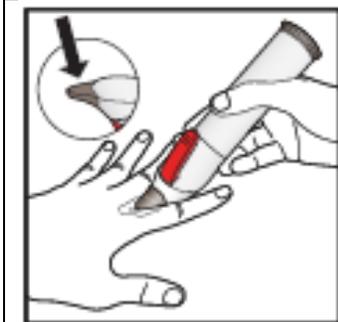
Applying Dovobet® gel to the affected area



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 gel.
Release the lever fully between each pump to get a full dispense.

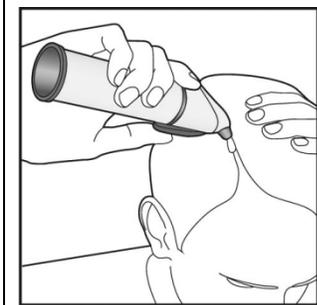
One full pump delivers 0.05 g of Dovobet® gel.



f. Use spreading surface to massage Dovobet® gel across plaques

Use the spreading surface to gently massage the gel into the affected skin.

Be careful not to press the lever when spreading.



g. To apply to scalp and hairline

Before applying Dovobet® gel to the scalp, comb the hair to remove any loose scales.

Tilt your head backwards to make sure the gel does not run onto your face.

Locate the area to treat using your fingers and part your hair. For a larger plaque or for very thick hair, you may need to re-part hair to expose neighbouring psoriasis area. Use the nozzle directly on the scalp to dispense and massage in the Dovobet® gel. Repeat until all affected scalp areas are covered.

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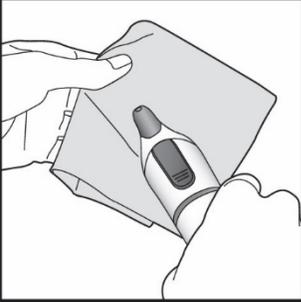
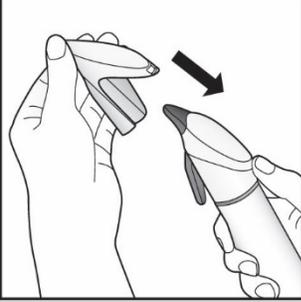
h. After application

Check that the entire affected areas are sufficiently covered by an even layer of Dovobet® gel. If needed, ask someone to help you apply Dovobet® gel to areas you cannot reach or see.

If you , or someone assisting you, gets Dovobet® gel on the fingers, wash your hands.

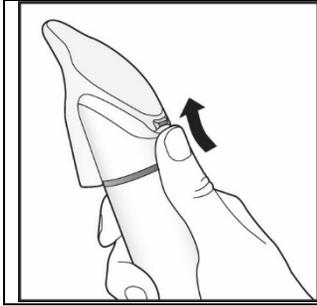
This will avoid accidentally spreading the gel to other parts of the body (especially the face, mouth and eyes)

After use

	<p>i. Clean your Applicator after each use</p> <p>Following use, wipe the applicator head (nozzle and flat spreading surface) with a clean, dry tissue. Avoid pumping while cleaning.</p> <p>Note:</p> <ul style="list-style-type: none"> • Do not wash the Applicator with water, detergents or any other substances. • Do not use moist or wet materials to wipe the Applicator.
	<p>j. Cover the Applicator for storage</p> <p>Replace the cover after each use to keep the applicator head clean.</p> <p>Always ensure the cover is clicked in place to prevent dispensing the product during storage and transportation.</p>
	<p>k. Estimate the amount of remaining Dovobet®</p> <p>To estimate the amount of remaining Dovobet® gel, look at the bottom of the cartridge to see the plunger position. The plunger moves upwards as gel is used.</p>

Before the next use

	<p>l. Check expiry date</p> <p>Always check the expiry date on the cartridge label before the next 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.</p>
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**m. Remove cover**

Remove the cover by lifting the tab at rear.
You are ready to use the applicator again.

Storage of your Applicator

Always ensure the cover is clicked in place to prevent dispensing the product during storage and transportation.
See also, Consumer Information under 'How to store Dovobet®'.

Disposal of your Applicator

The Applicator is disposable and should be disposed of when the cartridge is empty or has passed the expiry date.