## 1.3.2 Patient Information Leaflet for Dovobet Gel

**SCHEDULING STATUS**

**S4**

**PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM**

**Dovobet Gel**

**Read all of this leaflet carefully before you start using Dovobet Gel:**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **Dovobet Gel** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

### 1. WHAT DOVOBET GEL CONTAINS

**Active ingredients:**

Each one gram of **Dovobet Gel** contains:

- 50 µg (microgram) of calcipotriol monohydrate.
- 0,5 mg of betamethasone as the dipropionate.

The other ingredients are all-rac-alpha-tocopherol, butylhydroxytoluene, castor oil, liquid paraffin, polyoxypropylene stearyl ether.

### 2. WHAT DOVOBET GEL IS USED FOR

Your doctor has prescribed **Dovobet Gel** as a topical treatment for your psoriasis.

## 3. BEFORE YOU USE DOVOBET GEL

**Do not use Dovobet Gel:**

- If you are hypersensitive (allergic) to calcipotriol, betamethasone or any of the other ingredients of **DOVOBET GEL** (see **WHAT DOVOBET GEL CONTAINS**).
- If you suffer from certain types of psoriasis like erythrodermic, exfoliative and pustular psoriasis (ask your doctor for more information concerning this).
- If you suffer from known disorders of calcium metabolism (an increase of calcium in your blood - this occurs because of the calcipotriol component).
- If you suffer from severe liver disorders or severe kidney disorders.
- If you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**).
- **I**f you are a child or adolescents below 18 years of age.
- As **Dovobet Gel** contains a strong steroid, do not use **Dovobet Gel** on skin affected by:

- Infections caused by viruses (e.g. cold sores or chicken pox).
- Infections caused by a fungus (e.g. athlete's foot or ringworm).
- Infections caused by bacteria or sores on the skin.
- Infections caused by parasites (e.g. scabies).
- Skin manifestations in relation to tuberculosis or syphilis.
- Perioral dermatitis (red rash around the mouth).
- Thin skin, easily damaged veins, stretch marks.
- Ichthyosis (dry skin with fish-like scales).
- Acne (pimples).
- Rosacea (severe flushing or redness of the skin on the face) with or without pimples on skin.
- Ulcers or broken skin.
- Itching of the anus (back passage) or genitals (sex organs).

**Take special care with Dovobet Gel:**

Before using **Dovobet Gel** tell your doctor or pharmacist if:

- You are using other medicines containing corticosteroids, as you may get side effects.
- You have used **Dovobet Gel** for a long time and plant to stop (as there is a risk your psoriasis will get worse or ‘flare up’ when steroids are stopped suddenly). Consult your doctor.
- You have diabetes mellitus (high blood sugar) as your blood sugar/glucose levels may be affected by **Dovobet Gel**.
- Your skin becomes infected, as you may need to stop your treatments.
- You have a certain type of psoriasis called guttate psoriasis (type of psoriasis which appears as small, red, separate spots on the skin, usually on the trunk, arms and legs).

If you do have an operation, inform your medical practitioner if you are using **Dovobet Gel**.

**Avoid using Dovobet Gel:**

- **On more than 30 % of your body or using more than 15 grams per day**.
- **Under a bathing cap, bandages or dressings as it increases the absorption of the steroid in Dovobet Gel.**
- **On large areas of damaged skin or skin folds (groin, armpits, under breast) as it increases the absorption of the steroid in Dovobet Gel.**
- **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.**

**Pregnancy and breastfeeding:**

You should not use **Dovobet Gel** if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using **Dovobet Gel**.

**Driving and using machinery:**

**Dovobet Gel** should not have any effect on your ability to drive and use machines.

**Important information about some of the ingredients of Dovobet Gel:**

**Dovobet Gel** contains butylhydroxytoluene (see **What Dovobet Gel contains**) which may cause local skin reactions or irritation to the eyes and mucous membranes.

**Taking other medicines with Dovobet Gel:**

Always tell your doctor if you are taking any other medicine. (This includes complementary or traditional medicines.)

## 4. HOW TO USE DOVOBET GEL

Do not share medicines prescribed for you with any other person.

Always use **Dovobet Gel** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Use **Dovobet Gel** once a day. It may be more convenient to use the **Dovobet Gel** in the evening.

Your doctor will tell you for how long you have to apply **Dovobet Gel**.

**Do not use more than 15 grams of Dovobet Gel in one day, and the area treated should not exceed 30 % of the total body surface.**

If you have the impression that the effect of Dovobet Gel is too strong or too weak, tell your doctor or pharmacist.

**How to apply Dovobet Gel:**

- Shake the bottle well before each use.
- Apply **Dovobet Gel** in a thin layer to the affected area using a clean finger. Wipe away any excess **Dovobet Gel** from non-psoriasis areas.
- **Avoid applying Dovobet Gel directly to face or eyes.**
- **Wash your hands after each use.** This will avoid spreading **Dovobet Gel** to other parts of the body (especially the face, mouth and eyes).
- You should not take a shower or bath immediately after application of Dovobet Gel in order to achieve an optimal effect.
- **You should not bandage or tightly wrap or cover the skin area where you have applied Dovobet Gel.**

**If you have scalp psoriasis:**

Before applying **Dovobet Gel** to the scalp, comb your hair to remove any loose scales. It is not necessary to wash your hair before applying **Dovobet Gel**.

1. Shake the bottle well before each use.
2. Apply a drop of **Dovobet Gel** to the fingertip and apply directly onto the affected area or where you can feel raised plaque, and rub it in gently.
3. Tilt your head to make sure **Dovobet Gel** does not run onto your face. It may help to part your hair before you use **Dovobet Gel**.
4. **Wash your hands after each use.**

**Depending on the affected area 1 g to 4 g (up to 1 teaspoonful) is enough.**

In order to achieve optimal effect, it is recommended that the hair is not washed immediately after application of **Dovobet Gel**.

Let **Dovobet Gel** remain on the scalp during the night or during the day.

When washing hair after application of **Dovobet Gel** the following instructions might be useful:

5. Apply a mild shampoo to the dry hair, especially to those areas where **Dovobet Gel** was applied.
6. Leave the shampoo on the scalp for a couple of minutes before washing.
7. Wash your hair as usually.

If necessary, repeat steps 5-7 once or twice.

**If you use more Dovobet Gel than you should:**

In the event of overdosage or, if you have used more than 15 g of **Dovobet Gel** in one day, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and any remaining **Dovobet Gel** with you, so the doctor knows what you have been using.

Excessive use of **Dovobet Gel** may cause a problem with calcium in your blood.

**Excessive and prolonged use of Dovobet Gel can also cause your adrenal glands (found near your kidney and producing hormones in your body) to stop working properly.**

**If you forget to use Dovobet Gel:**

Use **Dovobet Gel** as soon as you remember on the same day. If it is almost time for your next usual application continue applying **Dovobet Gel** at your regular time. Do not apply a double dose to make up for forgotten applications.

**Effects when treatment with Dovobet Gel is stopped:**

Your doctor will tell you how long to use **Dovobet Gel**. Your condition may return if you stop using **Dovobet Gel** before you are told to do so.

**If your doctor advises you to stop using Dovobet Gel, it may be necessary to stop Dovobet Gel gradually, especially if you have used it for a long time.**

## 5. POSSIBLE SIDE EFFECTS

**Dovobet Gel** can have side effects.

Not all side effects reported for **Dovobet Gel** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using **Dovobet Gel**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using **Dovobet Gel** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are very serious side effects. If you have them, you may have had a serious allergic reaction to **Dovobet Gel**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

*Less frequent:*

- Excessive use of **Dovobet Gel** may cause the level of calcium in your blood or urine to increase, causing increased secretion of urine, constipation, muscle weakness, confusion and coma.
- Your adrenal glands may stop working properly and cause symptoms such as tiredness, depression and anxiety.
- Increase in pressure inside the eye, causing eye pain and red eyes.
- Cataracts (causing clouding of the eye's natural lens, causing loss of vision).
- Any signs of infection.
- If you are diabetic, you may experience changes in your blood glucose levels.
- A red area with yellowish pustules usually on the hands or feet.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:

*Less frequent:*

- Eye irritation.
- Burning sensation of the skin.
- Skin pain or irritation.
- Inflammation of the hair root.
- Rash, with inflammation of the skin.
- Redness of the skin.
- Acne (pimples).
- Dry, itchy skin.

- Worsening of your psoriasis while **Dovobet Gel** is used, or after treatment with **Dovobet Gel** has stopped (rebound effect).

The following less frequent side effects may be experienced if **Dovobet Gel** is used for a long time:

- Thinning of the skin.
- Appearance of veins on the skin surface or stretch marks.
- Changes in hair growth.
- Red rash around the mouth.
- Skin rash with inflammation or swelling.
- Golden coloured gel-filled bumps appearing on the skin.
- Lightening of skin colour.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## 6. STORING AND DISPOSING OF DOVOBET GEL

- Store at or below 30 °C.
- Do not refrigerate
- Keep the bottle well closed.
- Keep in the outer carton to protect from light.
- Use within 6 months after first opening.
- **STORE ALL MEDICINES OUT OF REACH OF CHILDREN**.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

## 7. PRESENTATION OF DOVOBET GEL

**Dovobet Gel** is packaged in either 30, 60 and 120 ml white high-density polyethylene bottles equipped with a low-density polyethylene nozzle and a high-density polyethylene red screw cap.

The bottles and package insert are contained in an outer unit carton with packaging sizes of 15 g, 30 g, and 60 g.

## 8. IDENTIFICATION OF DOVOBET GEL

An almost clear, colourless to slightly off-white lipophilic gel. A thin oily layer may occur on the top.

## 9. REGISTRATION NUMBER

46/13.9.1/0615

## 10. NAME AND ADDRESS OF REGISTRATION HOLDER

Adcock Ingram Limited

1 New Road

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## 11. DATE OF PUBLICATION

Date of registration: 29 March 2019

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