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| Applicant/PHCR:           | Macleods Pharmaceuticals SA (Pty) Ltd        |
| Product Proprietary Name: | Clobetasol propionate 500 µg/g topical spray |
| Active Ingredient:        | Clobetasol propionate                        |
| Dosage Form:              | Topical spray                                |
| Date:                     | 30 June 2026                                 |

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## APPROVED PATIENT INFORMATION LEAFLET JUNE 2026

**SCHEDULING STATUS:** S4

### **MAKLOVATE 500 µg/g SPRAY**

One gram of cutaneous spray solution contains 500 micrograms of clobetasol propionate.

**Read all of this leaflet carefully before you start taking MAKLOVATE 500 µg/g SPRAY**

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

**MAKLOVATE 500 µg/g SPRAY** 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.

#### **What is in this leaflet**

1. What **MAKLOVATE 500 µg/g SPRAY** is and what it is used for
2. What you need to know before you take **MAKLOVATE 500 µg/g SPRAY**
3. How to take **MAKLOVATE 500 µg/g SPRAY**
4. Possible side effects
5. How to store **MAKLOVATE 500 µg/g SPRAY**
6. Contents of the pack and other information

#### **1. What MAKLOVATE 500 µg/g SPRAY is and what it is used for**

**MAKLOVATE 500 µg/g SPRAY** contains a medicine called Clobetasol propionate. It belongs to a group of medicines called steroids. It helps to reduce swelling and irritation.

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**MAKLOVATE 500 µg/g SPRAY** is used to treat plaque-type psoriasis of moderate to severe intensity in adults. Psoriasis is caused by your skin cells being produced too quickly.

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## 2. What you need to know before you take MAKLOVATE 500 µg/g SPRAY

### Do not use MAKLOVATE 500 µg/g SPRAY:

- if you are allergic (hypersensitive) to clobetasol propionate or any of the other ingredients of this medicine (listed in Section 6)
- If you are hypersensitive to other corticosteroids
- If you have bacterial, viral, fungal or parasitic skin infections such as cold sores, chicken pox, shingles, impetigo (a type of rash on the face), ringworm, athlete's foot, thrush, skin tuberculosis or skin disease caused by syphilis.
- If you have skin conditions such as acne, rosacea (severe flushing of skin on and around the nose), perioral dermatitis (spotty red rash around the mouth).
- If you have weeping wounds.
- In children and adolescents.
- If you are pregnant (see section 4.6)
- If you are breastfeeding (see section 4.6)
- Do not apply **MAKLOVATE 500 µg/g SPRAY** to or in your eyes or eyelids (due to risk of glaucoma which is high pressure in the eye and risk of cataract), around genital organs or around the anus

Do not use if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before using **MAKLOVATE 500 µg/g SPRAY**.

### Warnings and precautions

Take special care with **MAKLOVATE 500 µg/g SPRAY**:

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Tell your doctor or health care provider before using **MAKLOVATE 500 µg/g SPRAY**:

Take special care with **MAKLOVATE 500 µg/g SPRAY**:

- When using **MAKLOVATE 500 µg/g SPRAY**, avoid contact with the eyelids, armpits and chapped skin. If any of this product gets into these regions, rinse it off with water immediately.
- If you get **MAKLOVATE 500 µg/g SPRAY** in your eye(s), wash the affected eye thoroughly with water. If any irritation persists, please seek advice from your doctor.
- If you experience newly developed bone pain or worsening of previous bone symptoms during a treatment with **MAKLOVATE 500 µg/g SPRAY** especially if you have been using **MAKLOVATE 500 µg/g SPRAY** for a prolonged time or repeatedly.
- If you use other oral/topical medication containing corticosteroids or medication intended to control your immune system (e.g. for autoimmune disease or after a transplantation). Combining **MAKLOVATE 500 µg/g SPRAY** with these medicines may result in serious infections.
- If you have previously had an allergic reaction with another steroid
- If you are applying the ointment on broken or damaged skin or within the skin folds.
- If you have psoriasis, your doctor will want to see you more often.
- If you are pregnant (see section 4.6)
- If you are breastfeeding (see section 4.6)
- If you are using around a chronic leg ulcer as you may be at increased risk of local allergic reaction or infection.
- If you are applying near eyes or on eyelids, as cataracts or glaucoma may result if the ointment repeatedly enters the eye.
- If you are applying to thin skin such as the face, as **MAKLOVATE 500 µg/g SPRAY** may cause

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skin thinning. Use on the face should be limited to 5 days. Dressings or bandages should not be used on the face where the ointment is applied.

- If an infection develops during the use of this medicine, talk to your doctor or pharmacist.
- Contact your doctor if you experience blurred vision or other visual disturbances.

Do not cover the treated areas with airtight dressings or bandage.

Make sure that the skin is cleansed before a fresh dressing is applied to prevent infections.

Do not use on large areas of the body.

Tell your doctor if you suffer from liver disease or diabetes as using **MAKLOVATE 500 µg/g SPRAY** when you have these long term conditions may require closer follow up by your doctor.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

#### *Use in children and adolescents*

- Do not use **MAKLOVATE 500 µg/g SPRAY** in adults under the age of 18 years.

#### **Other medicines and MAKLOVATE 500 µg/g SPRAY**

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

#### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine

#### *Pregnancy*

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Do not use **MAKLOVATE 500 µg/g SPRAY** if you are pregnant. Ask your doctor or pharmacist for advice before using **MAKLOVATE 500 µg/g SPRAY**.

#### *Breastfeeding*

Do not use **MAKLOVATE 500 µg/g SPRAY** if you are breastfeeding your infant. Ask your doctor or pharmacist for advice before using **MAKLOVATE 500 µg/g SPRAY**.

#### **Driving and using machines**

**MAKLOVATE 500 µg/g SPRAY** should not affect your ability to drive or use machines.

**MAKLOVATE 500 µg/g SPRAY** contains ethanol (49,25 % w/w).

### **3. How to take MAKLOVATE 500 µg/g SPRAY**

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

Always use **MAKLOVATE 500 µg/g SPRAY** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

Make sure your skin is clean and dry before spraying **MAKLOVATE 500 µg/g SPRAY** directly onto your affected skin areas twice a day, taking care to spray well to all the affected areas and massage in until the product has all disappeared. Do not use large amounts of **MAKLOVATE 500 µg/g SPRAY**; only use enough to cover the affected skin areas. Wash your hands thoroughly after spraying unless it is being used for treating your hands.

Your doctor will tell you how long you need to use **MAKLOVATE 500 µg/g SPRAY** for, to control your psoriasis. Treatment should not continue for more than 4 weeks and should be limited to a maximum of 50 g (corresponding to 1 bottle of 60 ml) per week of **MAKLOVATE 500 µg/g SPRAY**. If no improvement is seen by the end of the treatment, please tell your doctor. This treatment needs careful

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supervision; you should let your doctor review your progress at regular intervals. Do not use **MAKLOVATE 500 µg/g SPRAY** for longer than 4 weeks.

If you have used **MAKLOVATE 500 µg/g SPRAY** for longer than you should, please see your doctor.

Do not swallow it.

If you or a child accidentally swallows **MAKLOVATE 500 µg/g SPRAY**, consult our doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

### **Method of administration**

For use on your skin only.

Do not use it more often than prescribed or use it for a long times (such as every day for many weeks or months). If you need treatment for a long time, your doctor may decide you need to use a milder treatment.

The germs that cause infections like warm and moist conditions under dressings. If directed to cover the treated area with a dressing, always clean the skin before a fresh dressing is put on to help prevent infection of the skin beneath the dressing.

Be very careful not to get the liquid in your eyes. Do not touch your eyes until you have washed your hands.

If you wash or shampoo your hair it should be dried before applying the liquid.

If you are applying the scalp application on someone else make sure you wash your hands after use or wear disposable plastic gloves.

This product is flammable. Keep the liquid away from open fire and flames and all sources of ignition, including smoking, during application and immediately after you've used it.

Do not dry your hair with a hairdryer.

### **Guidance on how to apply the liquid**

1. Wash your hands.

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2. Unscrew the bottle cap and place the nozzle directly on the scalp that needs treating.
3. Gently squeeze the bottle to cover the area with a thin and even layer of liquid.
4. You can rub this liquid in, but you don't have to. Your scalp will feel cool until the liquid has dried.

Wash your hands again.

Do not exceed the prescribed amount.

If you have the impression that the effect of **MAKLOVATE 500 µg/g SPRAY** is too strong or too weak, talk to your doctor or pharmacist.

**If you use more MAKLOVATE 500 µg/g SPRAY than you should**

**MAKLOVATE 500 µg/g SPRAY** is not to be taken by mouth and is for use on the skin only.

If, in the rare event that **MAKLOVATE 500 µg/g SPRAY** is accidentally swallowed, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

**If you forget to use MAKLOVATE 500 µg/g SPRAY**

If you forget to use **MAKLOVATE 500 µg/g SPRAY**, do not use a double dose on the next application to make up for a forgotten dose. Go back to your regular schedule. If you miss several doses, tell your doctor.

**If you stop using MAKLOVATE 500 µg/g SPRAY**

If you stop using **MAKLOVATE 500 µg/g SPRAY**, please see your doctor. Worsening of your skin condition may occur when treatment with **MAKLOVATE 500 µg/g SPRAY** is stopped. Tell your doctor if you notice a worsening of your skin conditions.

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#### 4. Possible side effects

**MAKLOVATE 500 µg/g SPRAY** can have side effects.

Not all side effects reported for **MAKLOVATE 500 µg/g SPRAY** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **MAKLOVATE 500 µg/g SPRAY**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using **MAKLOVATE 500 µg/g SPRAY** and tell your doctor immediately or go to the casualty department at your nearest hospital:

swelling of the eyelids, face or lips as you may be allergic to the product.

These are all very serious side effects. If you have them, you may have had a serious reaction to **MAKLOVATE 500 µg/g SPRAY**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

*Frequent side effects:*

- burning sensation around the treated areas
- visible small blood vessels
- thinning skin
- inflammation of the hair follicle
- pain or irritation around the treated areas

*Less frequent side effects:*

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- itching and dryness around the treated areas
- rash
- erythema
- hypersensitivity reaction
- adrenal suppression
- Cushing syndrome
- allergic contact dermatitis
- psoriasis (aggravation)

*Frequency unknown*

- skin discolouration
- blurred vision

If you have a burning sensation or redness on the areas that have been treated, do not use **MAKLOVATE 500 µg/g SPRAY** until these symptoms have disappeared.

Repeated courses of **MAKLOVATE 500 µg/g SPRAY** over a long time may cause thinning of skin, stretch marks, surface veins, skin redness, bruising and local allergic reactions especially when treated areas are covered with airtight dressings or bandages.

The application on the face of very strong corticosteroids like **MAKLOVATE 500 µg/g SPRAY** may cause a spotty red rash around the mouth, thinning of skin or may worsen rosacea (severe flushing of skin on and around the nose).

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

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Should your general health worsen or if you experience any untoward effects while taking **MAKLOVATE 500 µg/g SPRAY**, please consult your healthcare provider for advice.

### **Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Macleods Pharmaceuticals SA (Pty) Ltd. at [safety@macleodspharma.com](mailto:safety@macleodspharma.com). By reporting side effects, you can help provide more information on the safety of **MAKLOVATE 500 µg/g SPRAY**.

### **5. How to store MAKLOVATE 500 µg/g SPRAY**

Store at or below 25 °C.

KEEP OUT OF THE REACH OF CHILDREN.

Store in the original package / container.

Keep tube tightly closed. Protect from light.

Do not store in a bathroom.

Do not use after the expiry date stated on the blister /label/carton bottle.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

### **6. Contents of pack and other information**

#### **What MAKLOVATE 500 µg/g SPRAY contains**

The active ingredient is clobetasol propionate.

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The other ingredients are: Alcohol, isopropyl myristate, sodium lauryl sulphate and undecylenic acid.

#### **What MAKLOVATE 500 µg/g SPRAY looks like and contents of the pack**

A clear colourless solution with no particulate matter.

#### **Contents of the pack:**

White HDPE bottle with a white polypropylene cap and white LDPE liner.

Pack size: 59 ml and 125 ml.

Not all pack sizes may be marketed.

#### **7. HOLDER OF CERTIFICATE OF REGISTRATION**

MACLEODS PHARMACEUTICALS SA (PTY) LTD

GROUND FLOOR, BLOCK 1,

BASSONIA ESTATE OFFICE PARK (EAST),

1 CUSSONIA DRIVE,

BASSONIA ROCK EXT 12

ALBERTON

GAUTENG

**This leaflet was last revised in**

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#### **Registration numbers**

**MAKLOVATE 500 µg/g SPRAY:** 58/13.4.1/0178

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Access to the corresponding Professional Information

The corresponding professional information can be accessed at

<https://www.macleodssaproducts.co.za> or email [macleodsrso@macleodspharma.com](mailto:macleodsrso@macleodspharma.com) or contact

011 682 1169.

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