

Applicant:	Galderma Laboratories South Africa (Pty) Ltd
Proprietary name:	CLOBEX SPRAY
Dosage form and strength:	Spray (0,5 mg/g Clobetasol propionate)
Registration Number	46/13.4.1/0556

PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS: S4

CLOBEX® SPRAY (spray solution)

Clobetasol propionate 500 µg/g

Read all of this leaflet carefully before you start using CLOBEX® 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
- **CLOBEX® 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 **CLOBEX® SPRAY** is and what it is used for
2. What you need to know before you start using **CLOBEX® SPRAY**
3. How **CLOBEX® SPRAY** is used
4. Possible side effects
5. How to store **CLOBEX® SPRAY**
6. Contents of the pack and other information

1. What CLOBEX® SPRAY is and what it is used for

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CLOBEX® SPRAY is a corticosteroid dermatological preparation.

CLOBEX® SPRAY is a steroid-type medicine used to treat plaque-type psoriasis of moderate to severe intensity in adults. Psoriasis is caused by your skin cells being produced too quickly.

2. What you need to know before you use **CLOBEX® SPRAY**

Always tell your health care provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby, please consult your health care provider for advice before using this medicine.

Do not use **CLOBEX® SPRAY**

- Hypersensitivity to the active or any of the excipients 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, athletes 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.
- Pregnancy (see section 4.6)
- Breastfeeding (see section 4.6)

Warnings and precautions

Take special care with **CLOBEX® SPRAY**:

Tell your doctor or health care provider before using **CLOBEX® SPRAY**:

- If you experience newly developed bone pain or worsening of previous bone symptoms during a treatment with **CLOBEX® SPRAY** especially if you have been using **CLOBEX® SPRAY** for a prolonged time or repeatedly.

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- 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 **CLOBEX® SPRAY** with these medicines may result in serious infections.
- Do not cover the treated areas with airtight dressings or bandage.
- Do not use on large areas of the body.
- When using **CLOBEX® 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 **CLOBEX® SPRAY** in your eye(s), wash the affected eye thoroughly with water. If any irritation persists, please seek advice from your doctor.
- Tell your doctor if you suffer from liver disease or diabetes as using **CLOBEX® SPRAY** when you have these long-term conditions may require closer follow up by your doctor.
- Pregnancy (see section 4.6)
- Breastfeeding (see section 4.6)

Children

Do not use **CLOBEX® SPRAY** in adults under the age of 18 years.

Other medicines and CLOBEX® SPRAY

Always tell your health care provider if you are taking or using any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy and Breastfeeding

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

Pregnancy

Do not use **CLOBEX® SPRAY** if you are pregnant. Ask your doctor or pharmacist for advice before using **CLOBEX® SPRAY**.

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Breastfeeding

Do not use **CLOBEX® SPRAY** if you are breastfeeding your infant. Ask your doctor or pharmacist for advice before using **CLOBEX® SPRAY**.

Driving and using machines:

CLOBEX® SPRAY should not affect your ability to drive or use machines.

CLOBEX® SPRAY contains ethanol (49,25 % w/w), isopropyl myristate, sodium laurilsulfate and undecylenic acid.

3. How CLOBEX® SPRAY is used

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

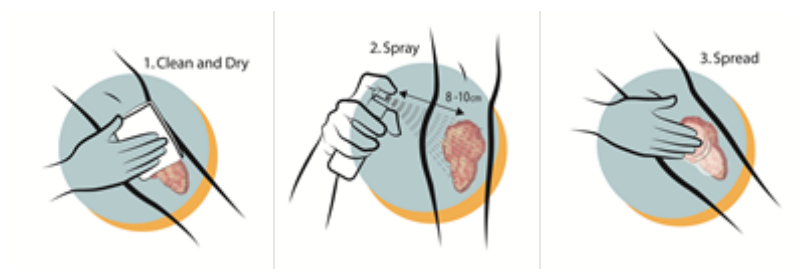
Always use **CLOBEX® SPRAY** exactly as your doctor has told you.

Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with **CLOBEX® SPRAY** will last.

If you have the impression that **CLOBEX® SPRAY** is too strong or too weak, tell your doctor or pharmacist.

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



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Your doctor will tell you how long you need to use **CLOBEX® 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 CLOBEX® SPRAY**.

If no improvement is seen by the end of the treatment, please tell your doctor. This treatment needs careful supervision; you should let your doctor review your progress at regular intervals. Do not use **CLOBEX® SPRAY** for longer than 4 weeks.

If you use more CLOBEX® SPRAY than you should

CLOBEX® SPRAY is not to be taken by mouth and is for use on the skin only.

If, in the rare event that **CLOBEX® SPRAY** is accidentally swallowed, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre

If you forgot to use CLOBEX® 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 CLOBEX® SPRAY

Please see your doctor. Worsening of your skin condition may occur when treatment with **CLOBEX® SPRAY** is stopped. Tell your doctor if you notice a worsening of your skin conditions.

4. Possible side effects

CLOBEX® SPRAY can have side effects.

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

You should stop using **CLOBEX® SPRAY** and consult your doctor immediately if you experience swelling of the eyelids, face or lips as you may be allergic to the product.

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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:

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

Frequency unknown side-effects:

- skin discolouration
- blurred vision

If you have a burning sensation or redness on the areas that have been treated, do not use

CLOBEX® SPRAY until these symptoms have disappeared.

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Repeated courses of **CLOBEX® 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 **CLOBEX® 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.

5. How to store CLOBEX® SPRAY

Store all medicines out of reach of children.

Keep the medicine in its original container.

Do not use **CLOBEX® SPRAY** after the expiry date which is stated on the bottle and the carton.

The expiry date refers to the last day of that month.

Store in the original package.

Store at or below 30 °C, do not refrigerate or freeze.

Do not remove the bottle from the carton until required for use.

Discard the bottle 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.

6. Contents of the pack and other information

What CLOBEX® SPRAY contains:

The active substance is clobetasol propionate.

Each gram of **CLOBEX® SPRAY** contains 500 micrograms of the active ingredient clobetasol propionate.

The other ingredients are:

ethanol (49,25 % w/w), isopropyl myristate, sodium laurilsulfate and undecylenic acid.

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What CLOBEX® SPRAY looks like and contents of the pack

CLOBEX® SPRAY is a clear colourless solution with no particulate matter

Pack contains:

CLOBEX® SPRAY is available on prescription from your doctor in white plastic bottles with a spray pump and white plastic cap.

Bottles contain 30 ml, 60 ml or 120 ml of cutaneous spray solution, packed in a carton box.

Holder of Certificate of registration:

Galderma Laboratories South Africa (Pty) Ltd

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2 Bruton Road

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2191

This leaflet was last revised in

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