

CONSUMER MEDICINE INFORMATION

Clobex[®] Shampoo

500mcg/mL clobetasol propionate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about CLOBEX SHAMPOO. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking CLOBEX SHAMPOO against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What CLOBEX SHAMPOO is used for

CLOBEX SHAMPOO is used as a topical treatment for moderate to severe scalp psoriasis in adults.

It belongs to a group of medicines called corticosteroids.

CLOBEX SHAMPOO is used on the scalp to relieve the redness, swelling, itching and discomfort of scalp psoriasis.

Your doctor, however, may have prescribed CLOBEX SHAMPOO for another purpose.

Ask your doctor if you have any questions about why CLOBEX SHAMPOO has been prescribed for you.

There is no evidence that CLOBEX SHAMPOO is addictive. CLOBEX SHAMPOO is available only with a doctor's prescription.

Before you use CLOBEX SHAMPOO

When you must not use it

Do not use CLOBEX SHAMPOO if:

- 1. you have ever had an allergic reaction to :**
 - medicines containing *clobetasol propionate*
 - any of the ingredients listed at the end of this leaflet
- 2. you have skin areas affected by bacterial, mycobacterial or viral skin infections (such as cold sores, shingles or chicken pox)**
- 3. you have skin areas affected by fungal or parasitic skin infections (such as thrush, tinea or ringworm)**
- 4. you have skin areas affected by specific skin**

diseases (such as skin tuberculosis or skin disease caused by lues)

- 5. you have skin areas with ulcerous wounds**

If you are not sure whether you should be using CLOBEX SHAMPOO, talk to your doctor.

Do not use CLOBEX SHAMPOO if the packaging is torn or shows signs of tampering.

Do not use CLOBEX SHAMPOO after the expiry date (EXP) printed on the box or bottle has passed. The expiry date refers to the last day of that month. If you use this medicine after the expiry date it may not work (as well).

Do not use CLOBEX SHAMPOO on children under 2 years. You should not use CLOBEX SHAMPOO on children aged 2 to 18 years unless directed by the child's doctor.

Growth retardation may be observed in children in case of systemic absorption of topical corticosteroids.

Before you start to use it

You must tell your doctor if:

- 1. you are allergic to any other medicines or other substances such as foods, dyes or preservatives.**

2. you are pregnant or plan to become pregnant

Your doctor will discuss the risks and benefits of using CLOBEX SHAMPOO when pregnant.

3. you are breast-feeding or plan to breast-feed

Your doctor will discuss the risks and benefits of using CLOBEX SHAMPOO when breast-feeding.

If you have not told your doctor about any of the above, tell them before you start using CLOBEX SHAMPOO.

Using other medicines

Tell your doctor if you are using creams, ointments or lotions or taking any other medicines. This includes any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking/using CLOBEX SHAMPOO with other medicines.

How to use CLOBEX SHAMPOO

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

CLOBEX SHAMPOO is for topical use on the scalp only.

How to use

CLOBEX SHAMPOO should be applied directly to a dry scalp once daily taking care to cover and massage into all lesions.

Using the measuring cup included, measure out 7.5mL which is sufficient to cover the scalp. This is the maximum amount to be used per day.

CLOBEX SHAMPOO should be left without covering for 15 minutes before rinsing.

As with any topical medication, wash hands carefully after application.

After 15 minutes, the product must be rinsed with water and / or can be washed by using an additional amount of regular shampoo if needed to facilitate washing. Then, hair can be dried as usual.

In order to avoid hair colour changes in hair that has been dyed, CLOBEX SHAMPOO should be thoroughly rinsed.

Avoid contact with the eyes. If you accidentally get CLOBEX SHAMPOO in your eyes, rinse out the eyes with water immediately.

It is important to use CLOBEX SHAMPOO exactly as your doctor has told you. If you use it less often than you should, it may not work as well and your skin problem may not improve. Using it more often than you should may not improve your skin problem any faster and may cause or increase side effects.

Use CLOBEX SHAMPOO at the same time every day.

How long to use it

Your doctor will tell you how long to use CLOBEX SHAMPOO. It should not be used continuously for more than 4 weeks.

Do not use CLOBEX SHAMPOO for longer than your doctor tells you.

If you use CLOBEX SHAMPOO for longer than your doctor tells you, the chance of side effects may increase. Prolonged and/or intensive treatment with CLOBEX SHAMPOO may cause suppression of the immune response, opportunistic infections and other skin conditions.

If you are not sure how long to use CLOBEX SHAMPOO, talk to your doctor.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Otherwise, use it as soon as you remember, and then go back to using your medicine as you would normally.

Do not use a double dose to make up for the dose that you missed.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you swallow it

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26 in Australia or 0800 764 766 in New Zealand), or go to casualty at your nearest hospital, if you think that you or anyone else may have swallowed CLOBEX SHAMPOO. Do this even if

there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep these telephone numbers handy.

While you are using CLOBEX SHAMPOO

Things you must do

Tell all doctors and pharmacists who are treating you that you are using CLOBEX SHAMPOO.

If you feel that CLOBEX SHAMPOO is not helping your condition, tell your doctor (or pharmacist).

Tell your doctor if, for any reason, you have not used CLOBEX SHAMPOO exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you become pregnant while using CLOBEX SHAMPOO, tell your doctor.

If you are or want to start breastfeeding, tell your doctor.

Things you must not do

Do not use CLOBEX SHAMPOO in or near the eyes and eyelids.

Do not give CLOBEX SHAMPOO to anyone else, even if they have the same symptoms as yours.

Do not use CLOBEX SHAMPOO to treat other complaints unless your doctor tells you to.

Things to be careful of

Do not use large amounts of

CLOBEX SHAMPOO for a long time.

Avoid contact with the eyes. If the shampoo accidentally comes in contact with the eyes, rinse out the eyes with water immediately.

If you use large amounts for a long time, the chance of absorption through the skin and the chance of side effects increases.

Ask your doctor if you are concerned about the length of time you have been using CLOBEX SHAMPOO.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using CLOBEX SHAMPOO.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

The more common side effects of CLOBEX SHAMPOO (occur in less than 1 in 10 patients) include:

- skin burning sensation
- acne/inflammation of hair follicles

Tell your doctor if you notice any of these and they worry you.

The uncommon side effects of CLOBEX SHAMPOO (occur in less than 1 in 100 patients) include:

- local signs of skin irritation

- itching of the skin
- hives
- small red or purple clusters on the skin
- skin becoming fragile and prone to tears and ulcerations
- skin discomfort
- pain of skin
- fluid retention under the skin (oedema)
- aggravation of psoriasis
- hair loss causing spot baldness
- dry skin
- eye stinging / burning
- eye irritation
- ocular tight sensation
- headache
- stretch marks
- rash

Post-marketing adverse event reports have also included

- erythema (redness)
- rash
- allergic contact dermatitis
- glaucoma
- hypersensitivity
- hypercortisolism (Cushing's syndrome)
- adrenal suppression

Some people may get other side effects while using CLOBEX SHAMPOO.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using CLOBEX SHAMPOO

Storage

Store in the original bottle.

Keep CLOBEX SHAMPOO in a cool, dry place where the temperature stays below 25°C. Do not store it, or any other medicine, in a bathroom or near a sink. Do not leave them in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep CLOBEX SHAMPOO where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

Discard 4 weeks after first opening.

If your doctor tells you to stop using CLOBEX SHAMPOO, or it has passed its expiry date, ask your pharmacist what to do with any left over.

Medicines should not be disposed of via wastewater or household waste.

Product description

What it looks like

CLOBEX SHAMPOO is a viscous, translucent colourless to pale yellow liquid shampoo with alcoholic odour.

CLOBEX SHAMPOO is packaged in high density polyethylene (HDPE) bottles of 60mL or 125mL fitted with polypropylene snap closures which contain 8 or 16 days' worth of treatment, respectively. The HDPE bottle of 30mL is fitted with polypropylene screw closure which contains 4 days' worth of treatment. Not all pack sizes may be marketed.

Ingredients

CLOBEX SHAMPOO contains the active ingredient clobetasol propionate 500mcg/mL.

1 millilitre of CLOBEX SHAMPOO contains 500micrograms of clobetasol propionate.

CLOBEX SHAMPOO also contains the following excipients:
ethanol, coco-betaine, sodium laureth sulfate, polyquaternium-10, sodium citrate, citric acid, purified water.

Sponsor/distributor

Galderma Australia Pty Ltd
Suite 4, 13B Narabang Way
Belrose NSW 2085
Ph. 1800 800 765

In New Zealand by:
Healthcare Logistics'
58 Richard Pearce Drive
Airport Oaks
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Telephone 0800 174 104

Made in France

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