

Desowen Lotion

0.5 mg/g desonide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DESOWEN lotion. 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 DESOWEN lotion 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 DESOWEN lotion is used for

DESOWEN lotion is used for the treatment of the redness, swelling and itching that is associated with a number of skin ailments such as eczema and psoriasis.

It acts by constricting the blood vessels of the skin and affects the release of natural chemicals which cause redness and swelling.

It belongs to a group of medicines called corticosteroids.

Your doctor, however, may have prescribed DESOWEN lotion for another purpose.

Ask your doctor if you have any questions about why DESOWEN lotion has been prescribed for you.

There is no evidence that DESOWEN lotion is addictive. DESOWEN lotion is available only with a doctor's prescription.

Before you use DESOWEN lotion

When you must not use it

Do not use DESOWEN lotion if:

- 1. you have ever had an allergic reaction to :**
 - medicines containing *desonide*
 - any of the ingredients listed at the end of this leaflet
- 2. you have skin areas affected by 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 acne or rosacea unless your doctor tells you to**
- 5. you have skin areas with ulcerous wounds**
- 6. you are going to have a bath, shower or are going swimming. If you do you may reduce the effectiveness of this product.**

If you are not sure whether you should be using DESOWEN lotion, talk to your doctor.

Do not use DESOWEN lotion if the packaging is torn or shows signs of tampering.

Do not use DESOWEN lotion 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 DESOWEN lotion on children under 2 years.

Growth retardation may be observed in children in case of systemic penetration of topical corticosteroids on large skin areas.

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.**

Your doctor will discuss the risks and benefits of using DESOWEN lotion when pregnant.
- 2. you are pregnant or plan to become pregnant**

Your doctor will discuss the risks and benefits of using DESOWEN lotion when breast-feeding.
- 3. you are breast-feeding or plan to breast-feed**

Your doctor will discuss the risks and benefits of using DESOWEN lotion when breast-feeding.

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

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 using DESOWEN lotion with other medicines.

How to use DESOWEN lotion

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.

DESOWEN lotion is for topical use only.

How to use

When using DESOWEN lotion, shake well before use.

Apply as a thin film to the affected areas two or three times each day depending on the severity of the skin problem.

DESOWEN lotion is for external use only.

DESOWEN lotion should not come into contact with the eyes, eyelids, lips, or the lining of the mouth or nose.

Do not apply to broken skin.

It is important to use DESOWEN lotion 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.

Do not use DESOWEN for more than 8 weeks.

Use in children strictly as directed by your doctor.

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

How long to use it

Your doctor will tell you how long to use DESOWEN lotion. It should not be used for more than 8 weeks.

Do not use DESOWEN lotion for longer than your doctor tells you.

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

If you are not sure how long to use DESOWEN lotion, 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), or go to casualty at your nearest hospital, if you think that you or anyone else may have swallowed DESOWEN lotion. 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 DESOWEN lotion

Things you must do

Tell all doctors and pharmacists who are treating you that you are using DESOWEN lotion.

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

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

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

If you become pregnant while using DESOWEN lotion, tell your doctor.

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

Things you must not do

Do not use DESOWEN lotion in or near the eyes and eyelids.

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

Do not use DESOWEN lotion to treat other complaints unless your doctor tells you to.

Things to be careful of

Do not use large amounts of DESOWEN lotion for a long time.

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

Tell your doctor if experience blurred vision or other visual disturbances after using DESOWEN lotion.

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 DESOWEN lotion.

Side effects

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

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 DESOWEN lotion (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 DESOWEN lotion (occur in less than 1 in 100 patients) include:

- local signs of skin irritation
- itching of the skin
- hives
- excessive hair growth over what is normally expected
- skin discolouration
- eczema
- skin becoming fragile and prone to tears and ulcerations
- skin lesions
- aggravation of rosacea
- dry skin
- eye stinging / burning
- eye irritation
- headache
- stretch marks
- rash including heat rash

Post-marketing adverse event reports have also included

- erythema (redness)
- facial swelling
- application site reaction
- rash
- severe itching
- blurred vision

Some people may get other side effects while using DESOWEN lotion.

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

After using DESOWEN lotion

Storage

Store in the original bottle.

Keep DESOWEN lotion in a cool, dry place where the temperature stays below 25°C. Do not freeze. 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 DESOWEN lotion 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

If your doctor tells you to stop using DESOWEN lotion, 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

DESOWEN lotion is a white to off-white, soft, smooth lotion.

DESOWEN lotion is packaged in high density polyethylene (HDPE) bottles of 10mL, 30mL, 60mL and 125mL. Not all pack sizes may be marketed.

Ingredients

DESOWEN lotion contains the active ingredient desonide 0.5mg/g.

DESOWEN lotion also contains the following excipients:

- sodium lauryl sulfate
- light liquid paraffin
- cetyl alcohol
- stearyl alcohol

- propylene glycol
- methyl hydroxybenzoate
- propyl hydroxybenzoate
- sorbitan monostearate
- self emulsifying glyceryl monostearate
- edetate sodium
- purified water
- citric acid
- sodium hydroxide

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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