

Kloxema Cream

Clobetasone butyrate 0.05 % w/w

CONSUMER MEDICINE INFORMATION

What is in this leaflet

Please read this leaflet carefully before you start using Kloxema Cream.

This leaflet answers some common questions about Kloxema cream.

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 or pharmacist has weighed the risks of you using Kloxema cream against the benefits they expect it will have for you.

Use Kloxema cream as instructed and follow the advice given in this leaflet.

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

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

What is Kloxema cream used for?

The name of your medicine is Kloxema cream. It contains the active ingredient Clobetasone butyrate at 0.05% w/w as the active ingredient.

Clobetasone butyrate belongs to the group of medicines called corticosteroids. It is used topically to control inflammation of the skin.

Kloxema cream is used to treat eczema and dermatitis, and can help to control patches of dry, red, itchy, flaky or inflamed skin caused by eczema or dermatitis.

Kloxema cream works to stop the skin's over-reaction to the triggers that cause skin flare ups. Kloxema cream suppresses the inflammation that causes eczema or dermatitis, and also has moisturising properties.

Your doctor or pharmacist, however, may have prescribed Kloxema cream for another purpose, so it is important to ask them any questions you have about why this medicine has been recommended for you.

Before using Kloxema cream

When you must not use this product

Do not use Kloxema cream if you have ever had an allergic reaction to:

- any medicine containing clobetasone butyrate
- any other corticosteroid, such as hydrocortisone, or similar medicines
- any of the ingredients in Kloxema cream listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not use Kloxema cream on:

- infected skin
- cuts or open wounds
- inflamed skin near ulcers

Do not use Kloxema cream to treat:

- acne, spots or pimples
- rosacea (skin condition of the face where the nose and cheeks are unusually red)
- pruritis (itching) with or without a rash

- perioral dermatitis
- untreated bacterial infections such as cellulitis (infection of the skin), folliculitis (infection of the hair follicle), furunculosis (boils) or impetigo (blisters)
- fungal infections such as athlete's foot and jock itch
- viral infections such as cold sores, chicken pox or shingles
- parasitic infestations such as scabies
- psoriasis unless recommended by your doctor.

If you have any of these conditions, ask your doctor or pharmacist for advice.

Precautions

Do not use on delicate skin areas such as the face, groin, genitals or between the toes.

Do not use KLOXEMA:

- if you are pregnant or may be pregnant
- if you are breastfeeding
- to treat any other conditions other than eczema and dermatitis unless advised by your doctor.

Do not use Kloxema cream on the wrong skin conditions.

It could make it worse.

If you are not sure what is causing your skin problem, ask your pharmacist or doctor.

Do not give Kloxema cream to anyone else, even if they have similar symptoms to you.

Do not use Kloxema cream after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start using this medicine, talk to your doctor or pharmacist.

Interactions

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you have kidney or liver problems.

If you have not told your doctor or pharmacist about any of the above, tell him/her before you start using Kloxema cream.

Tell your doctor or pharmacist about any other medicines you are taking including medicines that you buy without a prescription, in a pharmacy, supermarket or health food shop.

Do not use other corticosteroids (like hydrocortisone) on the skin while you are using this cream. You would be doubling the dose.

Some medicines and Kloxema cream may interfere with each other. These include:

- other corticosteroid medicines which may include some eczema creams, asthma inhalers, tablets, injections, nasal sprays, and eye or nose drops.
- ritonavir (antiviral medicine) and itraconazole (antifungal agent)

These medicines may affect the way Kloxema cream works.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

Pregnancy and lactation

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant or are breastfeeding. You should not use Kloxema cream if you are pregnant or may be pregnant or if you are breastfeeding unless advised by your doctor.

Your doctor or pharmacist will discuss the possible risks and benefits of using Kloxema cream during pregnancy or breastfeeding.

Use in Children

Do not use Kloxema cream on children under 12 years of age except on the advice of a doctor or pharmacist.

How to use Kloxema cream

Directions

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information in this leaflet.

If you do not understand the instructions on the carton or in this leaflet, ask your doctor or pharmacist for help.

How much to use

The minimum amount of cream should be used for the minimum amount of time. Do not use for more than 7 days.

- Squeeze out the cream along the top of your index finger (see picture)
- From the crease in the finger, squeeze the cream halfway to your fingertip. This will cover a patch of skin the same size as the palm of your hand
- Use the fingertip unit as a guide. For smaller areas, use a smaller amount. This cream is not meant to treat large areas

Half a fingertip will cover a patch of skin the same size as the palm of your hand.

- Don't cover the treated patch of skin with anything (bandages, dressings, gloves or plastic wrap). It can cause more of the medicine to pass through the skin.

How to use it

Adults or children over 12 years of age:

- Use the cream twice a day for up to 7 days
- Wash your hands and dry them
- Squeeze out the correct amount of cream to cover the affected area onto your index finger. (The picture above gives you an idea of how much to use).
- Gently rub cream onto the patch of skin you are treating.
- Wash your hands again (unless it is your hands you are treating).

Be especially careful not to get the cream in your eyes.

Use in children under 12 years of age only on the advice of a doctor.

When to use it

Use your medicine at about the same time each day.

Using it at the same time each day will have the best effect. It will also help you remember when to use it.

How long to use it

Use Kloxema cream twice a day for up to 7 days. Do not use for more than 7 days except on the advice of a doctor.

If you forget to use it

If you forget to use Kloxema cream or miss an application, use it as soon as you remember.

Do not try to make up for missed applications by using the cream more often as this may increase the chance of you getting a side effect.

If you have any questions, including if you have trouble remembering when to use your medicine, ask your doctor or pharmacist.

While you are using Kloxema cream

Things you must do:

Inform any other doctors, dentists or pharmacists who are treating you that you are using Kloxema cream.

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are using Kloxema cream.

If you become pregnant while using this medicine, tell your doctor or pharmacist immediately.

If your rash/ irritation gets better but then comes back tell your doctor or pharmacist.

Don't treat the same patch more than twice without taking advice from your doctor.

It is possible that you are treating the wrong skin condition or that your skin may still be reacting to something that it is coming in contact with. Some of the common triggers are:

- Earrings or studs - especially gold-plated earrings
- Other jewellery
- Coins
- Watch buckles, metal straps or the metal back of a watch
- Metal studs or fastenings on jeans, bras or underwear

All of these may have a metal in them called nickel that is a very common trigger. If you react badly to nickel, all of the triggers in the list could be a problem.

Other common triggers include rubber and pine tree sap, which are used in things we touch every day. You might find triggers:

- In the home: such as plasters, furniture polish, varnishes, rubber gloves or elastic in clothes.
- In substances you use at work: like glues, oils, lubricants or cement.
- In the garden: certain plants and weeds, gardening gloves.

Even if it is not practical to avoid triggers, there are often practical steps you can take to minimise possible irritation.

Kloxema cream is meant to control skin conditions that improve within a week of treating yourself. If you think you need further treatment after that, see a doctor for advice. Do not keep on using it.

If your skin gets worse or it does not improve within a week, stop using the cream and see your doctor.

If your skin condition clears up in less than a week, stop using the cream. Think about emollient (moisturising) products to help stop it coming back.

Skin specialists often advise people with eczema or dermatitis to use emollient (or moisturising) skin products, including creams and bath oils, to keep moisture in the skin. This can make your skin more resistant to flare ups. Avoid using soap and heavily scented products. Ask your doctor or pharmacist for further information.

Things you must not do:

Do not use Kloxema cream to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Side effects

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

Kloxema cream helps most people with eczema and dermatitis, but it may have unwanted side effects in a few

people. This cream is very unlikely to cause any problems as long as you follow the advice in this leaflet.

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

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

If your skin gets worse during treatment, you may have a skin infection or a trigger you have not recognised or even an allergy to the cream.

Stop using the cream and see your doctor as soon as possible.

Tell your doctor or pharmacist if you notice any of the following:

- rash
- itch
- local skin burning
- skin thinning
- skin bleaching or increased skin pigmentation and hair disorders

Worsening of eczema or dermatitis symptoms has also been reported.

Other side effects not listed above may also occur in some people.

Using more than the correct amount of cream may cause changes to your skin e.g. thinning or allow the active ingredient to pass through the skin and affect other parts of the body.

This is not a problem if you use the right amount of cream and for the correct period of time.

The following are very rare side effects and may occur if you use more than the correct amount of cream or for longer than recommended:

If you use more than the correct amount of cream or for longer than recommended you may experience:

- increased weight
- moon face or rounding of the face
- obesity
- changes to the colour of your skin
- increased body hair

The following symptoms may occur with use in children:

- delayed weight gain
- slow growth

Other side effects that may show up in blood tests or when your doctor gives you a medical examination:

- a decrease in the level of the hormone cortisol in your blood
- high blood pressure
- cloudy lens in the eye (cataract)
- increase pressure in the eye (glaucoma)
- weakening of the bones through gradual loss of mineral (osteoporosis). Additional tests may be needed after your medical examination to confirm if you have this condition
- increased blood sugar levels
- glucose in the urine.

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

In case of overdose

If you use a bit too much of the cream by mistake, don't worry but try to keep to the fingertip unit. Using corticosteroids on the skin continuously over many weeks or months can cause skin thinning and permanent damage.

If you swallow it

If you or anyone swallow Kloxema cream;

Immediately telephone your doctor or Poisons Information Centre for advice (in Australia telephone 13 11 26, in New Zealand telephone 0800 764 766) or go to Accident &

Emergency at your nearest hospital, even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Storage

Keep your cream in the pack until it is time to use it.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store Kloxema cream or any other medicine in the bathroom or near a sink.

Do not leave Kloxema cream or any other medicines in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep Kloxema cream 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.

Shelf life

Do not use Kloxema cream after the expiry date on the tube end or carton.

Disposal

If your doctor or pharmacist tells you to stop using Kloxema cream or the medicine has passed the expiry date, ask your pharmacist what to do with any medicine that is left over.

Product description

Kloxema cream is a white glossy cream packed in a 30g tube.

Kloxema cream contains:

- Clobetasone butyrate (active, 0.05% w/w)
- Water - purified
- Glycerol
- Glyceryl monostearate
- Cetostearyl alcohol
- Beeswax - synthetic
- Dimeticone 20
- Arlacel 170-PA(SG) (ARTG 108500)
- Sodium citrate
- Citric acid
- Methyl hydroxybenzoate

- Propyl hydroxybenzoate

For further information

This is not all the information that is available on Kloxema cream.

If you have any questions or are not sure about anything, ask your doctor or pharmacist.

Manufacturer

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Australia.

Australian Registration number:

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