

CUTIVATE CREAM

Fluticasone propionate (0.05% w/w)

What is in this leaflet

1. What Cutivate is used for
2. How Cutivate works
3. Before you use Cutivate
4. How to use Cutivate
5. While you are using it
6. Side Effects
7. Storage and Disposal of Cutivate
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Cutivate is used for

The name of this medicine is Cutivate Cream. Cutivate is used to reduce the risk of chronic atopic eczema from coming back once an acute episode has been treated effectively. Cutivate relieves the inflammatory and itching manifestations of corticosteroid-responsive skin problems. These include:

- eczema
- chronic itchy skin such as prurigo, neurodermatoses including lichen simplex and lichen planus
- seborrhoeic dermatitis (a red, scaly, itchy and stubborn dandruff that mainly affect the scalp)
- discoid lupus erythematosus (recurring scaly rash)
- used in addition to oral or injectable steroids for generalised erythroderma (widespread redness and scaling of the skin due to inflammatory skin disease)
- contact sensitivity reactions
- prickly heat
- insect bite reactions
- psoriasis (thickened rough patches of inflamed red skin, often covered by fine silvery scales)

For babies above three months and children Cutivate is used for skin inflammation that has not responded to milder steroid creams or ointments.

How Cutivate works

Cutivate contains fluticasone propionate which belong to a group of medicines called steroids. Steroids help to reduce redness, swelling and irritation of the skin.

Before you use Cutivate

- When you must not use it

Do not use Cutivate to treat any of the following skin problems, it could make them worse:

- infected skin (unless the infection is being treated with an anti-infective medicine at the same time)
- acne
- rosacea (a facial skin condition where the nose, cheeks, chin, forehead or entire face are unusually red)
- rashes around the mouth
- itchy skin which is not inflamed
- itching around the anus or genitals (penis and vagina)
- on babies under three months old

If you think any of these apply to you, do not use Cutivate until you have checked with your doctor or pharmacist.

- Before you start to use it

Tell your doctor if you are allergic (hypersensitive) to Cutivate or any of the ingredients.

If your children are over 3 months, they are more likely to develop local and systemic side

effects of topical corticosteroids and, in general, require shorter courses and less potent agents than adults.

In infants and children under 12 years of age, long-term continuous topical corticosteroid therapy should be avoided where possible, as adrenal suppression is more likely to occur.

If you are elderly, the greater frequency of decreased liver or kidney function may delay elimination if systemic absorption occurs.

If you have kidney or liver impairment, metabolism and elimination may be delayed therefore increasing the risk of systemic toxicity. Therefore the minimum quantity should be used for the shortest duration.

If you apply to a large surface area, it may result in increased systemic effects.

If you use on broken skin or other conditions where the skin barrier may be impaired, it may result in increased systemic effects.

If used in psoriasis, careful supervision is important.

If you are pregnant, or think you could be, or if you are planning to become pregnant, do not use Cutivate without talking to your doctor first.

If you are breast-feeding, you must check with your doctor before you use Cutivate.

If you do use Cutivate when breast-feeding, do not use

Cutivate on your breast area to ensure that the baby does not accidentally get Cutivate in their mouth.

- Taking other medicines

Some medicines may affect how Cutivate works, or make it more likely that you will have side effects. Examples of these medicines include:

- Ritonavir (antiviral medication) and itraconazole (antifungal medication)

Tell your doctor or pharmacist if you are taking any of these. There are other medicines which may have a similar effect. It is therefore very important to tell your doctor or pharmacist if you are taking any other medicines, if you have taken any recently, or if you start taking a new medicine. This includes medicines bought without a prescription.

How to use Cutivate

- How much to use

Use Cutivate once or twice a day. The number of times you use your medicine may be reduced as your skin gets better or your doctor may prescribe a weaker steroid for you to use instead.

How to use

- Apply a thin layer and gently rub in, using only enough to cover the entire affected area.
- Wash your hands after use unless treating the hands.
- If you are also using an emollient (moisturising) preparation allow time for Cutivate to be absorbed after each application before applying the emollient.
- This medicine should not be used every day for more than four weeks at a time.

If your eczema flares up frequently your doctor may suggest that you use a less frequent dose of Cutivate once your eczema is under control, to help stop your eczema from coming back.

For example, your doctor may advise you to apply a thin film of Cutivate once daily, two times a week to areas of skin which have been affected by eczema, or to those areas where it is likely to re-appear.

- When to use it

Always use Cutivate exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- How long to use it

If you use Cutivate regularly make sure you talk to your doctor before you stop using it.

- If you forget to use it

If you forget to use Cutivate apply it as soon as you remember then continue as before.

Do not apply extra Cutivate to make up for missed doses.

- If you use too much (overdose)

If you apply a large amount of Cutivate or accidentally swallow a lot of Cutivate, it could make you ill. If you do swallow a large amount of Cutivate, rinse your mouth out with plenty of water and contact your doctor or pharmacist for advice.

While you are using it

- Things you must do

Only use Cutivate for as long as your doctor recommends. If your condition does not improve

after 2-4 weeks of treatment, speak to your doctor.

If you experience blurred vision or other visual disturbances, speak to your doctor.

Take care when applying Cutivate to the eyelids to make sure it does not get into your eye.

Take care when applying Cutivate to the face over a long period of time as it may cause skin thinning.

If you have eczema around a leg ulcer use of a topical corticosteroid may increase the risk of an allergic reaction or an infection around the ulcer.

Only use an airtight dressing over this medicine if your doctor has told you to. If you are applying Cutivate under an airtight dressing, including a child's nappy, make sure that the skin is cleaned before a fresh dressing is applied to prevent infections.

Contact your doctor if an infection develops.

Whilst using Cutivate, do not smoke or go near naked flames due to the risk of severe burns. Fabric (clothing, bedding, dressing etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor. Do not take any new medicines without consulting your doctor.

Do not give Cutivate to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Cutivate cream contains the ingredient imidurea. Your body can break down imidurea into small amounts of chemical called formaldehyde. This chemical may cause a skin reaction including allergic sensation or irritation.

Side effects

Like all medicines Cutivate can have side effects although not everybody gets them.

Side effects will affect your skin and may affect other parts of your body if a sufficient quantity of medicine is absorbed through the skin and enters your blood stream.

If your skin condition gets worse or your skin becomes swollen during treatment. You may be allergic to the medicine, have an infection or need other treatment. Stop using Cutivate and tell your doctor as soon as possible.

Common side effects

These may affect up to 1 in 10 people:

- itching

Uncommon side effects

These may affect up to 1 in 100 people:

- local skin burning

Very rare side effects

These may affect up to 1 in 10,000 people:

Use of Cutivate for a long period of time, or use under an airtight dressing, may cause the following symptoms:

- increased weight
- moon face / rounding of the face

- obesity
- skin thinning, this may cause stretch marks
- the appearance of blood vessels under the surface of your skin
- changes to the colour of your skin
- increased body hair.

Other very rare skin reactions that may occur are:

- allergic reaction at the site of application
- worsening of condition
- redness
- rash or hives
- If you have psoriasis you may get raised bumps with pus under the skin. This can happen very rarely during or after treatment and is known as pustular psoriasis.
- skin infection.

In children also look out for the following symptoms:

- delayed weight gain
- slow growth.

Very rare 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
- increased levels of sugar in your blood or urine
- high blood pressure
- cloudy lens in the eye (*cataract*)
- increased 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.

Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome,

or if you notice any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Cutivate

- Storage

Keep out of the reach and sight of children. It may harm them. Don't use after the expiry date shown as "Exp" on the carton and label. Store below 30°C

- Disposal

Do not dispose of medicines in wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

Product Description

- What it looks like

Homogenous, white to off-white, smooth cream available in tubes of 15g.

- Ingredients

- Active ingredient(s)

Fluticasone propionate 0.05% w/w

- Inactive ingredient(s)

Liquid paraffin
Cetostearyl alcohol
Isopropyl myristate
Cetomacrogol 1000
Propylene glycol
Imidurea
Sodium phosphate
Citric acid monohydrate
Purified water

For important information about some of these ingredients see section “**While you are using it**”

- MAL number
MAL19960955ARZ

Manufacturer

Glaxo Wellcome Operations,
Barnard Castle, UK

Product Registration Holder

GlaxoSmithKline
Pharmaceutical Sdn. Bhd.
HZ.01, Horizon Penthouse,
1 Powerhouse,
1, Persiaran Bandar
Utama, Bandar Utama,
47800 Petaling Jaya
Selangor, Malaysia

Date of Revision

08/03/2024

Serial Number

NPRA(R1/3)14032023/062