

U-CLOSONE CREAM

Clobetasone Butyrate (0.05% w/w)

What is in this leaflet

1. What U-Closone Cream is used for
2. How U-Closone Cream works
3. Before you use U-Closone Cream
4. How to use U-Closone Cream
5. While you are using it
6. Side effects
7. Storage and Disposal of U-Closone Cream
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

This leaflet answers some common questions about U-Closone Cream. It does not contain all the available information. It does not take the place of talking to your pharmacist or doctor.

All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of you taking U-Closone Cream against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What U-Closone Cream is used for

U-Closone Cream is used to treat of skin disease in which inflammation is the prominent feature. These skin problems include all types of eczema and dermatitis and insect bite reactions.

How U-Closone Cream works

U-Closone Cream contains Clobetasone Butyrate. It belongs to a group of steroid called corticosteroids.

It has anti-inflammatory, relieves itching and blood vessels narrowing.

Before you use U-Closone Cream

-When you must not use it

Do not take U-Closone Cream if:

- You are hypersensitive to Clobetasone Butyrate or any of this medicine related ingredients.
- You have viral skin infections (e.g. herpes simplex, chicken pox), fungal, yeasts or bacterial infection (e.g. candidiasis, tinea, impetigo), skin condition that gives flushed appearance at the face, acne, rash around mouth and severe itching around the anus and genital.

-Before you start to use it

Tell your pharmacist or doctor:

- If you are applying the cream under an airtight dressing, including a child's nappy. These dressings make it easier for the active ingredient to pass through the skin. It is possible to accidentally end up using too much cream.

Pregnancy and breast feeding:

Safety of its use during pregnancy has not been established. Topical steroids should not be used extensively in pregnancy, i.e. in large amounts or for prolonged periods.

It is also not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Nevertheless, caution should be exercised when topical corticosteroids are prescribed for a nursing mother.

Ask your doctor or pharmacist for advice before taking this medicine if you are pregnant or breast-feeding.

-Taking other medicines

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

How to use U-Closone Cream

-How much to use

Apply a thin film of U-Closone Cream to the affected area up to 4 times a day or as directed by your doctor and pharmacist.

-When to use it

Apply up to four times daily until condition improves, then reduce frequency.

-How long to use it

Treatment should not normally exceed 7 days.

-If you forget to use it

Use it as soon as you remember, then carry on as before.

-If you use too much (overdose)

Corticosteroid applied to the skin can absorb in sufficient amount to produce systemic effect such as adrenal gland suppression, manifestation of Cushing's syndrome, high blood sugar level and presence of sugar in the urine.

If the adrenal gland suppression is found, then the medicine should be withdrawn, frequency of application reduced or a weaker steroid used.

If you suspect that you are overdosed, please consult your pharmacist or doctor. Bring any remaining medicine with you.

While you are using U-Closone Cream

-Things you must do

If you are about to start taking on any other new medicine, tell your pharmacist or doctor that you are taking U-Closone Cream.

-Things you must not do

Do not take more than the recommended dose unless your doctor tells you to.

-Things to be careful of

Appropriate treatment should be given in the presence of infections. If there is no favorable response, treatment with the corticosteroid

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should be discontinued until the infection has been controlled.

Special care must be taken when treating infants and children patients as systemic absorption can occur in topical administration causing growth retardation. In infants and children, long-term continuous topical corticosteroid therapy should be avoided where possible, as adrenal suppression can occur even without occlusion. Thus suitable precautions should be taken during prolonged treatment, when treating extensive body surface areas, and when treating children (because of a larger skin surface area to body weight ratio).

Suitable precautions should also be taken when treating stasis dermatitis and other skin diseases with impaired circulation.

Discontinue use if irritation, sensitivity or other reactions develop and consult your doctor.

Use with care if applied on the eyelids as glaucoma (increase pressure in the eyes) might result.

Prolonged application to the face should be avoided. Long-term continuous topical therapy should be avoided. Do not use in or around the eyes.

Side effects

Like all medicines, U-Closone Cream can cause side effects, although not everybody gets them.

Reported local adverse reactions are burning, itching, irritation, dryness, inflammation of hair follicles, excessive growth of hair, eruptions of acne, lightening of skin colour, softening and breaking down of the skin, secondary infection, thinning of the skin, stretch mark and heat rashes.

Large doses of corticosteroids may produce symptoms typical of low activity of the adrenal gland, with moon face, sometimes with abnormal growth of hair on face

and body in women, lump of fat that develop at top of the back between the shoulders, flushing, sometimes leading to a fully developed Cushing's syndrome.

If you get any side effects, even those not mentioned in this leaflet, tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of U-Closone Cream

-Storage

Store below 30°C.
Keep container well closed.
Protect from strong light.
For external use only.
Keep out of reach of children.

-Disposal

Dispose the medicine after the expiry date. 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.

Product description

-What it looks like

U-Closone Cream is a white cream.

U-Closone Cream available in aluminium tubes of 5g, 15g and 100g.

-Ingredients

-Active ingredient(s):
Each tube contains Clobetasone Butyrate 0.05 % w/w.

-Inactive ingredients:
Chlorocresol, Dimethicone, Glyceryl Monostearate PEG-100 Stearate, Glycerin, Cetostearyl Alcohol, Glyceryl Monostearate, Sodium Citrate, Purified Water.

-MAL number:

MAL20020807AZ

Manufacturer

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Product Registration Holder:

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