

UNIDERM CREAM

Clobetasol propionate (0.05% w/w)

What is in this leaflet

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

What Uniderm is used for

Uniderm contains a medicine called Clobetasol propionate. It is a very active topical corticosteroid which is of particular value when used in short courses for the treatment of more resistant skin conditions such as psoriasis (raised, rough, reddened areas covered with dry, fine silvery scales), (excluding widespread plaque, psoriasis), recalcitrant eczemas (itchy skin condition with redness, swelling, oozing of fluid, crusting which may lead to scaling), lichen planus (chronic itchy skin of unknown origin), discoid lupus erythematosus (recurring scaly rash), and other skin conditions which do not respond satisfactorily to less active steroids.

How Uniderm works

Clobetasol propionate in Uniderm is a highly active corticosteroid with topical anti-inflammatory activity. Clobetasol propionate reduces inflammation and can help to relieve the symptoms of inflammatory skin problems.

Before you use Uniderm

– When you must not use it

- Rosacea (facial redness)
- Acne
- Perioral dermatitis (inflammation of the skin around the mouth)
- Perianal and genital pruritus (intense itchiness in the anal and genital areas)
- Viral skin infections e.g. herpes simplex, chickenpox.
- Hypersensitivity to the preparation.

The use of Uniderm is not indicated in the treatment of primary infected skin lesions caused by infection with fungi (e.g. candidiasis, tinea) or bacteria (e.g. impetigo); or skin disorder in children under one year of age, including skin inflammation or napkin eruptions.

– Before you start to use it

- If Uniderm is required for use in children, it is recommended that the treatment should be reviewed weekly. It should be noted that the infant's napkin may act as an occlusive dressing.
- If Uniderm does enter the eye, the affected eye should be bathed in copious amounts of water.
- Topical steroids may be hazardous in psoriasis for a number of reasons including rebound relapses, development of tolerance, risk of generalized pustular psoriasis (rare widespread blister filled pus) and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis, careful supervision is important.
- Appropriate antimicrobial therapy should be used whenever treating inflammatory lesions which have become infected. Any spread of infection requires withdrawal of topical corticosteroid therapy and antimicrobial injections taken.
- Bacterial infection is encouraged by the warm, moist conditions induced by occlusive dressing, and so the skin should be cleansed before fresh dressing is applied.
- There is inadequate evidence of safety in human pregnancy, therefore, topical steroids should not be used extensively in pregnancy, i.e. in large amounts or for prolonged periods.
- The safe use of Clobetasol propionate during lactation has not been established.

– Taking other medicines

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

How to use Uniderm

– How much to use

Apply sparingly to the affected area once or twice daily until improvement occurs.

– When to use it

Use as directed by your doctor or pharmacist.

In every resistant lesions, especially where there is thickening of skin outer layer, the anti-inflammatory effect of Uniderm Cream can be enhanced if necessary by occluding the treatment area with polythene film. Overnight occlusion only is usually adequate to bring about a satisfactory response. Thereafter improvement can usually be maintained by application without occlusion.

– How long to use it

If no improvement is seen within two to four weeks, reassessment of the diagnosis, or referral, may be necessary.

– If you forget to use it

Apply it as soon as possible. Do not apply if almost time for the next dose; do not apply double doses.

– If you use too much (overdose)

In the case of chronic overdosage or misuse, the features of hypercortisolism (e.g. moon face, stretch mark, skin thinning) may appear and in this situation topical steroids should be reduced or discontinued gradually, under medical supervision.

While you are using it

– Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Uniderm.

Tell your doctor immediately if you become pregnant while taking this medication.

– Things you must not do

Long-term continuous therapy should be avoided where possible, particularly in infants and children, as adrenal suppression can occur even without occlusion.

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Things to be careful of

If used in childhood or on the face, courses should be limited if possible to five days and occlusion should not be used.

The face, more than other areas of the body, may exhibit atrophic changes after prolonged treatment with strong topical corticosteroids. This must be borne in mind when treating such conditions as psoriasis, discoid lupus erythematosus and severe eczema.

If applied to the eyelids, care is needed to ensure that the preparation does not enter the eye, as glaucoma (increased pressure in the eye) might result.

Side effects

Local hypersensitivity reactions such as redness, skin rash, itching, hives, local skin burning and allergic contact skin inflammation may occur at the site of application and may resemble symptoms of the condition under treatment.

Prolonged use of large amounts or treatment of extensive areas can result in sufficient systemic absorption to produce the features of hypercortisolism or Cushing's syndrome. This effect is more likely to occur in infants and children, and if occlusive dressings are used.

Prolonged and intensive treatment may cause local atrophic change; such as, thinning, stretch mark and dilation of the superficial blood vessel, particularly when occlusive dressings are used or when skin folds are involved.

There are reports of skin color change and hair overgrowth (hypertrichosis) with topical steroids.

If signs of hypersensitivity appear, application should be stopped immediately. Exacerbation of underlying symptoms may occur.

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 Uniderm

Storage

Store at temperature of not more than 30°C in a well-closed container.

Disposal

Medicines should not be disposed of via waste water 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

White, odorless, smooth, viscous cream. It is supplied as tube (Aluminum) 15 grams.

Ingredients

– Active ingredient

The active ingredient is Clobetasol propionate. Each 1 g of cream contains 0.5 g of Clobetasol propionate (0.05% w/w).

– Inactive ingredients

The other ingredients are cetomacrogol 1000, cetostearyl alcohol, white petrolatum, liquid paraffin, glycerin, propylene glycol, disodium phosphate anhydrous, citric acid, germaben II and purified water

MAL number:

MAL07090893AZ

Manufacturer

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Product Registration Holder

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