

# CLOBUTRATE CREAM 0.05% w/w

Clobetasone Butyrate 0.05% w/w

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## What Clobutrate Cream 0.05% w/w is used for

Clobutrate Cream relieves the symptoms of certain skin problems. These include:

- atopic eczema
- skin inflammation including seborrhoeic dermatitis (scaly patches, red skin and stubborn dandruff that mainly affect the scalp) and a type of skin reaction triggered by exposure to sunlight (photodermatitis)
- skin rash due to allergy or a substance that irritates your skin (irritant and allergic contact dermatitis)
- nappy rash
- inflammation of the outer ear canal
- prurigo nodularis (itchy nodules on the skin)
- insect bites

## How Clobutrate Cream 0.05% w/w works?

Clobutrate cream contains a medicine called clobetasone butyrate. It belongs to a group of medicines called steroids. It helps to reduce swelling and irritation.

## Before you use Clobutrate Cream 0.05% w/w

- When you must not use it
  - If you are allergic (hypersensitive) to Clobetasone Butyrate or any of the other ingredients of Clobutrate Cream 0.05% w/w.

- If you are planning to use it for the treatment of untreated cutaneous infection, rosacea (redness of skin), acne vulgaris, pruritus without inflammation.

### - Before you start to use it

You must tell your doctor if:

- you have allergies to any medicine which you have taken previously to treat your current condition.
- you are pregnant, trying to become pregnant or breast-feeding.

### *Pregnancy and breastfeeding*

Safety of its use during pregnancy and breastfeeding have not been established. Women who are pregnant and breastfeeding should consult a doctor before use.

If used during breastfeeding, the cream should not be applied to the breasts to avoid accidental ingestion by the infant.

Administration of Clobutrate cream during pregnancy and lactation should only be considered if the expected benefit to the mother outweighs the risk to the infants.

### - Taking other medicines

Co-administered drugs that can inhibit an CYP3A4 (an enzyme in the body) (e.g. ritonavir, itraconazole) have been shown to inhibit the metabolism of corticosteroids leading to increased systemic exposure.

Always inform your doctor and pharmacist if you are taking any other medicines, including herbal tonics, supplements and medicines that you buy without prescription.

## How to use Clobutrate Cream 0.05% w/w

Always use this medicine exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. Do not take this medication by mouth. This medication is for external use only.

### - How much to use it

Apply to the affected area up to four times daily until improvement is seen; then reduce frequency of application.

### - When to use it

Use as directed by your doctor or pharmacist.

### - How long to use it

The duration of the treatment depends upon the type of condition. You should apply the cream for as long as your doctor or pharmacist recommends it but do not exceed the recommended dosage.

### - If you forget to use it

- If you forget a dose, apply it as soon as you remember it.
- However, if it is nearly time for the next dose, skip the missed dose.
- Do not apply a double dose to make up for a forgotten dose.

### - If you use too much (Overdose)

Corticosteroid applied to the skin can be absorbed in sufficient amount to produce systemic effect. The features of hypercortisolism may occur in the case of chronic overdosage or misuse. In the case of overdosage, the cream should be withdrawn gradually by reducing the frequency of application or by substituting a less potent corticosteroid.

## While you are using it

### - Things you must do

- Tell your doctor if you have a history of local hypersensitivity to other corticosteroids.
- A shorter treatment should be given to children and infants as they are more likely to develop systemic adverse reactions due to their higher surface area to body mass ratio.
- Long term topical corticosteroid application should be avoided for infants and children under 12 years of age as adrenal and

growth suppression is more likely to occur.

- The skin should be cleaned first before using occlusive dressing. This is to reduce the risk of bacteria infection caused by the warm, moist conditions within skin folds or caused by occlusive dressing.
- Caution should be taken during the application to the eyelids. The cream must not enter the eye as cataract and glaucoma might result from repeated exposure.
- 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 treatment of appropriate antimicrobial therapy by your doctor.
- Avoid prolonged duration of use. Contact your doctor if your symptoms worsen or they do not improve.

- Things you must not do

Do not give Clobutrate Cream 0.05% w/w to anyone else, even if their symptoms seem similar or they have same condition as you. Your doctor has prescribed Clobutrate Cream 0.05% w/w for you and your condition.

- Things to be careful of

- Cushing's syndrome and Reversible hypothalamic-pituitary-adrenal (HPA) axis suppression leading to glucocorticosteroid insufficiency can occur due to increased systemic absorption of topical steroids. If any of the above are observed, reduce the frequency of application or substitute to a less potent corticosteroid.
- Clobutrate Cream 0.05% w/w contains cetostearyl alcohol which may cause local skin reactions and chlorocresol which may cause allergic reactions.

- The risk factors that increase systemic effects including potency and formulation of topical steroid, duration of exposure, application to a large surface area, application on occluded areas of skin or under occlusive dressing ( e.g. napkin used in infant can be considered as an occlusive dressing), increasing hydration of the stratum corneum (outermost layer of the skin), use on thin skin area or on broken skin or impaired skin barrier.
- Topical corticosteroids used to treat the dermatitis around chronic leg ulcer may increase the risk of local hypersensitivity reactions and local infection.
- Clobutrate Cream 0.05% w/w is strictly for external use only. It should be kept out of reach of children. In case of accidental ingestion, you must consult to a doctor immediately.

**Side Effects**

Like all medicines, Clobutrate Cream 0.05% w/w 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 Clobutrate cream and tell your doctor as soon as possible.

Other side effects may include:

- an increased risk of skin infection.
- an allergic skin reaction where the cream is applied.
- a feeling of burning, irritation or itching where the cream is applied.
- Rash, itchy bumpy skin or redness of the skin.
- Increased hair growth and changes in skin colour
- Thinning of your skin and it may also damage more easily
- Weight gain, rounding of the face
- Delayed weight gain or slowing of growth in children

- Bones can become thin, weak and break easily
- Cloudy lens in the eye (cataract) or increased pressure in eye (glaucoma)
- Increased blood sugar levels or sugar in the urine
- High blood pressure

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 calling Tel: 03-78835550, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my)

(Public → Reporting Side Effects to Medicines → ConSERF).

**Storage and Disposal of Clobutrate Cream**

- Storage

Do not use after the expiry date stated on the pack. The expiry date refers to the last day of that month.

Clobutrate Cream 0.05% w/w should be stored in the original package and in a dry place.

Do not store above 30°C.

**Keep out of the reach and sight of children.**

- Disposal

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

A smooth white cream in aluminium tubes with white caps.

They are supplied in 15g of collapsible aluminium tubes.

- Ingredients

-Active Ingredient:

Each gram of product contains 0.5mg of the active substance, Clobetasone Butyrate.

-Inactive ingredients:

The other ingredients are Polysorbate 60, Glycerin, White Petrolatum, Cetostearyl Alcohol, Citric Acid Hydrous, Sodium Citrate and Chlorocresol.

- MAL number:

**Manufacturer and Product  
Registration Holder**

Malaysian Pharmaceutical Industries  
Sdn. Bhd.

Plot 14, Lebuhraya Kampung Jawa,  
11900 Bayan Lepas, Penang, Malaysia.

**Date of Revision**

23/11/2017