BEZONE CREAM

Betamethasone Valerate (0.1% w/w)

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What Bezone Cream is used for

Betamethasone Valerate is the active ingredient of Bezone Cream. It belongs to a group of medicines called steroids.

It is indicated for relief or acute or chronic inflammatory manifestation of skin responding to corticosteroids such as dermatitis, psoriasis, xerosis and pruritus.

It is also indicated in allergic contact dermatitis or irritant dermatitis. In addition, the cream will cool and dry the acute inflammatory and exudative lesions.

How Bezone Cream works Valerate Betamethasone is corticosteroid and is used for its antiinflammatory, antipruritic (relieve itching) and vasoconstrictive (constriction of blood vessel) action on the skin.

Before you use Bezone Cream

- When you must not use it
 - If you are allergic (hypersensitive) to Betamethasone Valerate or any of the other ingredients of Bezone Cream.
 - If you have a skin viral disease such as varicella and vaccina.

- 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.

- <u>Taking other medicines</u>

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 Bezone Cream

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

- How much to use

Adults

The cream is applied to the affected area two to four times daily

Children

The cream is applied to the affected area once a day.

Occlusive dressing:

Gently rub a small amount of the cream to the affected area until it disappears. Re-apply the cream leaving a thin coating on the affected area and covered by piece of polyethylene sheet, or, for the hands and feet, polyethylene gloves or bags. As much as possible, the air skin between the and polyethylene is expelled and the dressing sealed with adhesive tape. This left up to 48 hours and if necessary, renewed after the skin has been gently washed and dried.

How should you use it

- 1. Wash your hands
- 2. Gently rub the correct amount of cream into the skin until it has all disappeared.
- 3. You can measure how much Bezone Cream to use with your fingertip.

When to use it

Use as directed by your doctor or pharmacist.

How long to use it

Continue using Bezone Cream for as long as your doctor recommends.

If you forget to use it

- If you forget a dose, use it as soon as you remember it.
- However, if it is nearly time for the next dose, skip the missed dose.
- Do not use a double dose to make up for a forgotten dose.
- If you use Bezone Cream regularly, make sure you talk to your doctor before you stop using it.

If you use too much (overdose)

Symptoms of toxicity that is associated with topical corticosteroids therapy may be characterised as either local or systemic. Symptoms are described under 'Side effects'.

Contact your doctor immediately or go to Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Contact your doctor if your symptoms worsen or they do not improve.

If you do become pregnant whilst using Bezone Cream, tell your doctor.

- <u>Things you must not do</u>

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

- Things to be careful of

Corticosteroids should not be used in the presence of infection.

Bezone Cream should not be applied with an occlusive dressing to large areas of the body because of the increased risk of systemic toxicity.

The cream should not be applied to ulcers of the leg.

Long term topical use is best avoided especially in children and during pregnancy.

Side effects

Like all medicines, Bezone Cream can have side effects, although not everybody gets them. The following side effects may happen with this medicine.

- Infection such as pain, redness or pus-containing blisters.
- Irritations such as burning, itching blistering, or peeling not present during therapy.
- Prolonged use and treatment of extensive areas will cause moon face (feature of hypercorticism), reddish purple lines on arms, legs, trunk and groin and thinning of skin with easy bruising.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Consult your doctor or pharmacist if you are in doubt or for any further information.

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 Bezone Cream

- <u>Storage</u>

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

Store at 15-25°C. Protect from heat and freezing.

Keep out of the reach and sight of children.

- <u>Disposal</u>

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 white cream base.

They are supplied in 15g of collapsible aluminium tubes.

- Ingredients
 - Active ingredient
 Each gram contains
 Betamethasone Valerate equivalent to Betamethasone 1mg.
 - Inactive ingredients
 The other ingredients are mineral oil heavy, white petrolatum, cetostearyl alcohol, cetomacrogol 1000, sodium phosphate anhydrous, citric acid hydrous and chlorocresol.
- <u>MAL Number</u> MAL19920300AZ

Manufacturer and Product Registration Holder

Malaysian Pharmaceutical Industries Sdn. Bhd.

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