

# Betasone Actavis Cream 0.1%w/w

Betamethasone [as 17-Valerate] (0.1% w/w)

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## What Betasone is used for

Betasone is used to help reduce the redness and itchiness of certain skin problems, such as eczema, psoriasis and dermatitis.

## How Betasone works

Betasone contains a medicine called Betamethasone (as 17-Valerate). It belongs to a group of medicines called steroids. It helps to reduce swelling and irritation.

## Before you use Betasone

### - When you must not use it

Do not use Betasone:

- If you are allergic (hypersensitive) to betamethasone
- on a child under 1 year
- to treat any of the following skin problems, it could make them worse:
  - acne
  - severe flushing of skin on and around your nose (rosacea)
  - spotty red rash around your mouth (perioral dermatitis)
  - itching around your back passage or private parts - unless your doctor has told you to do so
  - viral infections, such as cold sores, herpes or chicken pox
  - fungal infections, such as ringworm, athlete's foot or thrush
  - skin blisters or sores that are caused by bacterial infections, such as impetigo.

Do not use if any of the above applies to you. If you are not sure, talk to your doctor or

pharmacist before using Betasone.

### - Before you start to use it

Check with your doctor or pharmacist before using your medicine 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.
- you have psoriasis, your doctor will want to see you more often.

### - Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription and herbal medicines.

## How to use Betasone

### - How much to use

Apply sparingly 2 - 3 times daily, reducing frequency as condition responds.

### - When to use it

Treatment should start as early as possible after the start of an infection.

### - How long to use it

Continue treatment for 5 days. Treatment may be continued for up to 10 days if healing has not occurred.

### - If you forget to use it

If you forget to use Betasone, use it as soon as you remember. However, if it is nearly time for your next application, skip the missed application.

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

If, by mistake on a few occasions you use more than you should, do not worry. If you apply a lot or a lot is accidentally swallowed, it could make you ill. Talk to your doctor or go to the hospital as soon as possible.

## While you are using it

### - Things you must do

Always wash your hands before and after you use the cream.

### - Things you must not do

It should not be used for more than 5 days, as the skin on your face thins easily. Do not let the cream get into your eyes.

Do not use it on children or infants unless directed by a doctor.

### - Things to be careful of

You should only apply the cream to your face if your doctor tells you to.

## Side Effects

Like all medicines, Betasone can cause side effects, although not everybody gets them. Stop using Betasone and tell your doctor as soon as possible if:

- you find that your skin condition gets worse or becomes swollen during treatment. You may be allergic to the Betasone, have an infection or need other treatment.
- 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.

Other side effects you may notice when using Betasone include:

### Common

- a feeling of burning, irritation or itching where the cream is applied. Side effects if you use Betasone for a long time, you use a lot each time you apply it, or you apply it under an airtight dressing.

### Very rare

- stretch marks may develop
- veins under the surface of your skin may become more noticeable
- 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 and high blood pressure. These are more likely to happen in infants and children.

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](http://npra.gov.my) [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

### **Storage and Disposal of Betasone**

#### - Storage

Keep all medicines out of the reach of children.

Keep below 30°C. Protect from light. Do not freeze.

#### - Disposal

Do not take this medicine after the expiry date stamped on the label.

Return any unused cream to your pharmacist to be disposed of. Only keep the cream if your doctor tells you to. Do not throw them away in your normal household drainage or waste. This will help to protect the environment.

### **Product Description**

#### - What it looks like

Non-greasy white cream.

#### - Ingredients

Active Ingredient

Betamethasone [as 17-Valerate]

BP 0.1% w/w.

Inactive ingredients

White soft paraffin , Light liquid paraffin , Cetostearyl alcohol , Cetomacrogol 1000 , Propylene glycol , Citric acid monohydrate , Sodium phosphate di-basic, Purified water, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate.

#### - MAL Number

MAL19890643AZ

### **Manufacturer**

PT Actavis Indonesia

Jl. Raya Bogor Km. 28,  
Kelurahan Pekayon, Kecamatan  
Pasar Rebo

Kota Jakarta Timur, Provinsi  
DKI Jakarta, Indonesia

### **Product Registration Holder**

DCH Auriga (Malaysia) Sdn.  
Bhd.

Lot 6, Persiaran Perusahaan  
Seksyen 23, 40300 Shah Alam  
Selangor, Malaysia

### **Date of Revision**

16/05/2023

### **Serial number**

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