

ROYCE BETASONE CREAM 0.1 % W/W

Betamethasone Valerate (0.1%w/w)

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What Royce Betasone Cream 0.1% w/w is used for

Betamethasone valerate is an active topical corticosteroid which produces a rapid response in those inflammatory skin conditions that are normally responsive to topical corticosteroid therapy.

How Royce Betasone Cream 0.1% w/w works

Betamethasone 17 Valerate is a topical corticosteroid and is an anti-inflammatory agent.

Before you use Royce Betasone Cream 0.1% w/w

-When you must not use it

Do not take Royce Betasone Cream 0.1% w/w if you:

- are pregnant.
- are breast-feeding.
- are allergic (hypersensitive) to Betamethasone or other ingredients in this product.

Ask your doctor or pharmacist for advice before taking any medicine.

-Before you start to use it:

Tell your doctor or pharmacist if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Facial redness.
- Acne and small bumps around the mouth.
- Skin lesions caused by infection with viruses (e.g. herpes simplex, chickenpox), fungi (e.g. candidiasis; tinea) or bacteria (e.g. impetigo).

-Taking other medicines:

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Betamethasone is often effective in the less responsive conditions and increased risk of low potassium level with amphotericin (avoid concomitant use unless corticosteroids required to control reactions).

How to take Royce Betasone Cream 0.1% w/w

-How much to use:

Your doctor or pharmacist can advise you how many doses are needed each day and for how long you may need to take it. This depends on your condition and whether or not you are taking any other medicines.

The recommended dosages are as follows:

For external use only.

A small quantity of Betasone should be applied to the affected area. Betasone Cream is especially appropriate for moist or weeping surfaces. In the more resistant lesions, such as the thickened skin of psoriasis on elbows and knees, the effect of Betasone can be enhanced, if necessary, by occluding the treatment area with polyethylene film. Overnight occlusion only is usually adequate to bring about a satisfactory response in such lesions; thereafter improvement can usually be maintained by regular applications without occlusion.

Use in children:

Use smallest amount for effective treatment. Children may be more susceptible than adults to adrenal gland suppression and Cushing's syndrome because of the larger ratio of surface area to body weight, increased pressure in the skull has also been observed in children receiving topical corticosteroids. Long term therapy may interfere with growth and development.

-When to use it:

To be used 1 to 3 times daily until improvement occurs. Follow the advice of your doctor or pharmacist.

-How long to use it:

Consult with your doctor or pharmacist for the treatment period.

-If you forget to use it:

If you forget to apply the cream, use it as soon as you remember. However, if it is almost time for your next application, wait until then to use the cream and skip the missed application. Do not apply extra cream to make up for missed application.

-If you use too much (overdose):

If you accidentally applied too many Royce Betasone Cream 0.1% w/w, wipe off the excess.

Symptom of Royce Betasone Cream 0.1% w/w overdose includes systemic absorption that may result in adrenal suppression (steroid hormone insufficiency).

While you are using Royce Betasone Cream 0.1% w/w

-Things you must do

- Use the cream exactly as your doctor described.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Royce Betasone Cream 0.1% w/w.
- Wash your hands before and after using this cream.

-Things you must not do

- Do not give Royce Betasone Cream 0.1% w/w to anyone else, even if they have the same symptoms or condition as you.
- Discontinue use if irritation or sensitivity reaction develops.
- Do not use Royce Betasone Cream 0.1% w/w for a long time of large amounts, or treatment of extensive areas particularly in infants and children, as adrenal suppression more likely to occur even without occlusion.

-Things to be careful of

- Application to the eyelids may cause increased pressure in the eye.
- If there is spread of infection, your doctor may discontinue the medicine and prescribe other medicine to treat the infection.
- Bacterial infection is encouraged by the warm, moist conditions induced

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by occlusive dressing, and the skin should be cleansed before a fresh dressing is applied.

- The face, more than other areas of the body, may exhibit skin changes after prolonged treatment with potent topical corticosteroid.
- Avoid extensive use in pregnancy.

Side effects

Like all medicines, Royce Betasone Cream 0.1% w/w can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any of the side effects after taking this medicine:

- Hypercorticism signs and symptoms:
 - Stretch mark may develop
 - Skin thinning and dilatation of the superficial blood vessels: veins under the skin's surface become more noticeable
 - high blood pressure
 - a round red face
 - a fat lump between the shoulders
 - weak muscles
 - weak bones
 - acne
 - fragile skin that heals poorly

The effect is more likely to occur in infants and children.

- Hypersensitivity: swollen skin.

In rare instances, treatment of psoriasis with corticosteroids (or its withdrawal) is thought to have provoked the pus from the disease.

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 [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Royce Betasone Cream 0.1% w/w

-Storage:

Keep container tightly closed. Store in a dry place below 30°C. Protect from light. Keep out of reach of children.

-Disposal:

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose

medicine no longer required. These measures will help to protect the environment.

Product description

What it looks like:

A white colour, smooth cream.

-Ingredients:

-Active Ingredients:

Betamethasone (17-Valerate).

-Inactive Ingredients:

Methyl paraben, propyl paraben, liquid paraffin, cetomacrogol, white soft paraffin, cetostearyl alcohol and purified water.

-MAL Number.:

MAL19870604AZ

Manufacturer and Product Registration Holder

Royce Pharma Manufacturing Sdn. Bhd.

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