

ROYCE HYDROCORTISONE ACETATE CREAM

Hydrocortisone Acetate (1% w/w)

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What Royce Hydrocortisone Acetate Cream 1% w/w is used for

For the treatment of skin inflammation such as:

- Eczema
- Prurigo;
- Neurodermatoses
- Discoid lupus erythematosus, generalized erythroderma.

How Royce Hydrocortisone Acetate Cream 1% w/w works

The active ingredient, hydrocortisone, is a corticosteroid that has an anti-inflammatory, anti-itch and blood vessel narrowing actions.

Before you use Royce Hydrocortisone Acetate Cream 1% w/w

-When you must not use it

Do not use Royce Hydrocortisone Acetate Cream 1% w/w if you have:

- Known allergies to hydrocortisone or any of the other ingredients used in this medicine.
- Skin lesion caused by infection with viruses (e.g. herpes simplex, chickenpox).
- Skin conditions caused by fungal (e.g. candidiasis, tinea) or bacterial infection (e.g. impetigo).

If you are not sure whether you should start using this medicine, talk to your doctor or pharmacist.

-Before you start to use it

- Do not use around eyes to avoid contact.
- Do not bandage or wrap the treated skin area unless directed to do so by physician. Avoid 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 cream.
- Tell your pharmacist or doctor if you have infection on your skin and specify on the infected area.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before using this medicine if you are pregnant or breast-feeding. It should not be used extensively on pregnant woman in large amounts or for prolonged periods of time. Caution should be exercised when used to nursing mothers.

-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.

How to use Royce Hydrocortisone Acetate Cream 1% w/w

-How much to use

Apply a small quantity of the cream to the affected area.

You should check with your doctor or pharmacist if you are not sure.

-When to use it

To be applied 2 – 3 times daily.

Please follow the advice of your doctor or pharmacist.

-How long to use it

Depending on the seriousness of the condition. Consult with your doctor if

your symptoms do not improve after treatment.

-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 Hydrocortisone Acetate Cream 1% w/w, wipe off the excess.

Excessive use of steroid cream may cause systemic absorption that may result in adrenal suppression.

While you are using it

-Things you must do

- Use the cream exactly as your doctor described.
- This medicine is for external use only.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Royce Hydrocortisone Acetate Cream 1% w/w.
- Wash your hands before and after using this cream.
- Discontinue use of any occlusive dressings and consult the doctor if skin infection occurs.

-Things you must not do

- Do not give Royce Hydrocortisone Acetate Cream 1% w/w to anyone else, even if they have the same symptoms or condition as you.
- Corticosteroid applied to the skin can be adsorbed in sufficient amounts to produce systemic effects such as suppression of hypothalamus, pituitary and adrenal gland activity, manifestation of Cushing's syndrome (excess level of cortisol hormone), high blood sugar and excretion of glucose in the urine.

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- Suitable precautions should be taken during prolonged treatment, when treating extensive body surface areas, when using the occlusive technique and when treating children (because of a larger skin surface area to bodyweight ratio).
- High pressure in the skull has also been observed in children receiving topical corticosteroids. Long term therapy may interfere with growth and development.

-Things to be careful of

- If irritation or sensitivity reaction occurs, stop using it and inform your doctor or pharmacist.

Side effects

Like all medicines, Royce Hydrocortisone Acetate Cream 1% w/w can cause side effects, although not everybody gets them.

Reported adverse reactions are local-burning, itching, irritation, dryness, hair follicle inflammation, abnormal hair growth, acne eruptions, lighting of the skin, small bumps around the mouth, allergic contact skin inflammation, secondary infection, skin thinning, stretch mark and heat rashes.

Local skin changes may occur where skin folds are involved, or in areas such as the nappy area in small children, where constant moist conditions favour the absorption of hydrocortisone.

Sufficient systemic absorption may also occur in such sites to produce the features of hypercorticism after prolonged treatment.

Hypercorticism: high blood pressure, a round red face, a fat lump between the shoulders, weak muscles, weak bones, and fragile skin and heals poorly. This effect is more likely to occur in infants and children, and if occlusive dressings are used.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website nptra.moh.gov.my [Consumers → Reporting Side Effects to Medicine (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Royce Hydrocortisone Acetate Cream 1% w/w

-Storage:

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

-Disposal:

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose the medicines you no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

A white colour, smooth cream.

-Ingredients

-Active ingredient:

Hydrocortisone acetate.

-Inactive ingredients:

Cholesterol, cetomacrogol, white soft paraffin, cetostearyl alcohol, methylparaben, propylparaben, glycerin, colloidal silicon dioxide and purified water.

-MAL Number:

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Manufacturer and Product Registration Holder

Royce Pharma Manufacturing Sdn. Bhd.

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