DIPROGENTA® CREAM

Betamethasone dipropionate/gentamicin sulfate (0.5 mg/1 mg)

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What Diprogenta Cream is used for

Diprogenta Cream is a medication used on the skin to treat bacterial infections, including eczema, dermatitis and psoriasis of the scalp, hands and feet as diagnosed by your doctor.

Eczema is a common skin disease, which causes the skin to become red and itchy. Dermatitis is inflammation of the skin. Psoriasis is a skin disease in which itchy, scaly, pink patches develop on the elbows, knees, scalp and other parts of the body.

How Diprogenta Cream works

Diprogenta Cream contains the active ingredients betamethasone dipropionate and gentamicin sulfate.

Betamethasone dipropionate belongs to a group of medicines called topical corticosteroids which are used on the surface of the skin to reduce the redness and itchiness caused by certain skin problems. Gentamicin belongs to a group of medicines called broad spectrum antibiotics and is effective in treating various types of common skin problems that are caused by bacterial infections.

Before you use Diprogenta Cream

- When you must not use it

Do not use Diprogenta Cream

- If you are allergic to any of the ingredients in this medicine (listed in "Ingredients").
- If you have skin problems such as vaccinia, varicella, and tuberculosis as told by your doctor.

- Before you start to use it

Talk to your doctor or pharmacist before using Diprogenta Cream. This medicine should not be used under bandages or occlusive dressings.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Children

If the cream is used more often than it should, or more than prescribed, it can affect some of your child's hormones. This may affect their growth and development.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

How to use Diprogenta Cream

- How much to use

A thin layer of Diprogenta Cream should be applied to the affected skin area twice a day, in the morning and at night.

- When to use it

Use as directed by your doctor. Frequency of application should be determined by your doctor.

- How long to use it

- Always use this medicine exactly as your doctor or pharmacist has told you.
 Duration of therapy varies depending upon the extent and location of the disease as well as patient response.
 Check with your doctor or pharmacist if you are not sure.
- If you have not used the cream as you were told to do and have used it too often and/or for a long time, you should tell your doctor or pharmacist as the chance of side effects may increase.
- If your skin condition does not improve by three to four weeks, you should tell you doctor or pharmacist.

- <u>If you forget to use it</u>

Consult your doctor or pharmacist on what you should do if you forget to use it. If you forget to use your cream at the right time, use it as soon as you remember, then carry on as before.

- If you use too much (overdose)

If you use the cream more often than you should, or on large areas of your body, it can affect some of your hormones and lead to unwanted side effects. In children this may affect their growth and development.

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While you are using Diprogenta Cream

- Things you must do

- Use your medicine exactly as your doctor has told you
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Avoid getting the cream in your eyes.
- This medication is to be used for the full prescribed treatment time, even though the symptoms may have improved.
- Do not share Diprogenta Cream with anyone else; it was prescribed only for you.

- Things to be careful of

Tell your doctor or pharmacist if you noticed any side effects while using the cream.

Side effects

Like all medicines, Diprogenta Cream can cause side effects, although not everybody gets them.

Diprogenta Cream is generally well tolerated. However rare side effects such as allergic reactions and reduced skin pigmentation have been reported:

Side effects reported with the used of gentamicin include:

- swelling,
- redness
- itchiness

Other side effects reported with the used of topical corticosteroid, especially if the cream is used under bandages or occlusive dressings include:

- burning
- itching
- irritation of the skin

- dryness of the skin
- spots that look like acne
- inflammation of the hair follicles
- excessive hair growth
- reduced skin pigmentation
- allergic reactions
- softening/breakdown of the skin
- infection of the skin
- thinning of the skin
- stretch marks
- sweat rash (small and itchy rashes on the skin)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible 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 (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety)

Storage and Disposal of Diprogenta Cream

- Storage
- Keep out of the reach and sight of children.
- Store below 30^oC.
- <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 does it looks like

Diprogenta Cream is a smooth, white and uniform cream, free from foreign matter.

It is available in 5 g, 15 g tubes and 450 g jars.

- Ingredients
- Active ingredients: bethamethasone dipropionate, gentamicin sulfate.
- Inactive ingredients: Chlorocresol, sodium phosphate monobasic monohydrate, phosphoric acid, white petrolatum, mineral oil, cetostearyl alcohol, ceteth 20, purified water.

- <u>MAL number:</u> MAL19871372AZ

Product Manufacturer

MERCK SHARP DOHME PHARMA Tbk

Jl. Raya Pandaan Km 48, Pandaan, Pasuruan, Jawa Timur, Indonesia

Product Registration Holder

Merck Sharp & Dohme (Malaysia) Sdn. Bhd.

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