

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

DIPROGENTA® Cream

DIPROGENTA® Ointment

Betamethasone (as dipropionate) 0,5 mg and gentamicin (as sulphate) 1 mg

Read all of this leaflet carefully before you start using DIPROGENTA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- DIPROGENTA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What DIPROGENTA is and what it is used for
2. What you need to know before you use DIPROGENTA
3. How to use DIPROGENTA
4. Possible side effects
5. How to store DIPROGENTA
6. Contents of the pack and other information

1. What DIPROGENTA is and what it is used for

DIPROGENTA contains a cortisone-type medicine with an aminoglycoside antibiotic.

DIPROGENTA is used to help relieve inflammation or discomfort associated with certain skin conditions (such as psoriasis, allergic disorders, eczema or other conditions) when infection is present or suspected.

2. What you need to know before you use DIPROGENTA

Do not use DIPROGENTA Cream and Ointment:

- If you are allergic (hypersensitive) to betamethasone dipropionate and gentamicin sulphate or any of the other ingredients of DIPROGENTA Cream and Ointment.
- If you are under the treatment of herpes infections, vaccine reactions, chicken pox (varicella) or tuberculosis of the skin.

Warnings and precautions

Take special care with **DIPROGENTA Cream and Ointment**

- DIPROGENTA is for use only on the skin. Avoid contact with the eyes. Use with particular caution on facial skin and only for short periods.
- Do not use DIPROGENTA on large areas of the body, as this will increase the amount absorbed.
- Do not use DIPROGENTA more often or for a longer time than your doctor recommends.
- Check with your doctor if your skin condition worsens.
- Do not use DIPROGENTA in any skin crease areas.
- Children and adolescents who must use DIPROGENTA should be followed closely by their doctor, since DIPROGENTA is absorbed through the skin and can affect growth or cause other unwanted effects. DIPROGENTA should ideally not be used in infants and young children at all.
- If you experience visual disturbances including blurred vision.

If there is a worsening of your condition during use consult your doctor – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment.

If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the cream without consulting your doctor unless your doctor has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

Other medicines and DIPROGENTA Cream and Ointment

Always tell your healthcare provider if you are taking any other medicine (this includes all complementary or traditional medicines).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using this medicine.

The use of DIPROGENTA is not recommended for mothers who are breastfeeding.

Driving and using machines

None stated.

3. How to use DIPROGENTA

Do not share medicines prescribed for you with any other person.

Always use DIPROGENTA exactly as your doctor has told you. You should check with your

doctor or pharmacist if you are not sure.

Apply a thin film of DIPROGENTA Cream or Ointment to cover the affected area and massage in gently, usually twice a day (morning and night) or as directed by your doctor. Mild cases may respond to once-a-day application.

Do not bandage or otherwise wrap the skin being treated unless directed to do so by your doctor. Do not use tight-fitting diapers or plastic pants on a child being treated with DIPROGENTA unless directed to do so by your doctor. Do not apply DIPROGENTA to deep skin wounds, puncture wounds, serious burns or raw areas.

If you have an impression that the effect of DIPROGENTA is too strong or too weak, talk to your doctor or pharmacist.

If you use more DIPROGENTA than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use DIPROGENTA

Do not use a double dose to make up for forgotten individual applications. If you miss one application, apply your next dose as usual.

If you stop using DIPROGENTA

If you stop using DIPROGENTA, you will lose the effects of this medicine. You should not stop using this medicine, unless your doctor tells you as your symptoms may return.

4. Possible side effects

DIPROGENTA can have side effects. The following have been reported and the frequencies

are unknown: burning, itching, irritated or dry skin, irritation or redness of the face, increased hair growth, acne, change in skin colour, thinning of skin with easy bruising, stretch marks, blurred vision or other signs of irritation not present before use of DIPROGENTA.

Steroid withdrawal reaction:

If used continuously for prolonged periods a withdrawal reaction may occur on stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using DIPROGENTA, please consult your healthcare provider for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of DIPROGENTA.

5. How to store DIPROGENTA

Store at or below 25°C.

Store all medicines out of the reach of children.

Do not use after the expiry date stated on the tube and on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DIPROGENTA contains

The active substances are 0,5 mg Betamethasone (as dipropionate) and 1 mg gentamicin (as sulphate).

DIPROGENTA Cream: The other ingredients are: Cetomacrogol 1000, cetostearyl alcohol, liquid paraffin, monobasic sodium phosphate, phosphoric acid, white soft paraffin and purified water.

Preservative: Chlorocresol 0,1 % *m/m*

DIPROGENTA Ointment: The other ingredients are: Liquid paraffin and white soft paraffin.

What DIPROGENTA looks like and contents of the pack

DIPROGENTA Cream is a smooth, white cream.

DIPROGENTA Ointment is a smooth, off-white ointment.

DIPROGENTA Cream and Ointment is packed in tubes of 20 g in cartons.

Holder of Certificate of Registration

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