

DIPROCEL OINTMENT

Betamethasone dipropionate (0.05% w/w)

What is in this leaflet

1. What Diprocel ointment is used for
2. How Diprocel ointment works
3. Before you use Diprocel ointment
4. How to use Diprocel ointment
5. While you are using Diprocel ointment
6. Side effects
7. Storage and Disposal of Diprocel ointment
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What DIPROCEL ointment is used for

Diprocel ointment is used to relieve the inflammation symptoms caused by certain skin problems responding to corticosteroid including resistant or severe psoriasis.

Psoriasis is a skin disease in which itchy, scaly, red patches develop on the elbows, knees, scalp and other parts of the body.

How Diprocel ointment works

Diprocel ointment contains the active ingredient betamethasone dipropionate.

Betamethasone dipropionate belongs to a group of medicines called topical corticosteroids which are used on the surface of the skin to reduce the inflammation and itchiness caused by certain skin problems.

Before you use Diprocel ointment

- When you must not use it

Do not use Diprocel ointment:

- If you are allergic (hypersensitive) to its active ingredient betamethasone dipropionate, or to any of its ingredients (See full list in "Ingredients"), or to similar medicines.

- Side effects that may happen with oral or injectable corticosteroids may also occur with topical corticosteroids, especially in infants and children.

- Before you start to use it

- Talk to your doctor or pharmacist before using Diprocel ointment.
- This medicine should not be used under bandages or plasters.

Pregnancy, breastfeeding and fertility

Medicines of this class should not be used on pregnant women in large amounts or for prolonged periods of time.

Caution should be exercised when Diprocel ointment is used to nursing women.

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

Do not put the ointment under your child's diaper as this makes it easier for the active ingredient of the medicine to pass through the skin and possibly cause some unwanted effects.

- Taking other medicines

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

How to use Diprocel ointment

- How much to use

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

A thin film of Diprocel ointment should be applied to cover completely the affected area.

- When to use it

Diprocel ointment should be applied once daily, in the morning. Diprocel ointment may also be applied two times daily, in the morning and at night, if you are told to do by your doctor.

- How long to use it

You should stop using Diprocel ointment when your skin problem is under control as directed by your doctor. How long you use Diprocel ointment will vary from a few days to a longer period of time. Do not use Diprocel ointment for longer than four weeks unless told to do so by your doctor.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Use the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to use the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

If you have not used the ointment 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.

While you are using Diprocel ointment

- Things you must do

- Tell your doctor or pharmacist if you have any other skin problem.

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- Take the ointment exactly as your doctor has told you.
- Tell your doctor immediately if you become pregnant while taking this ointment.
- If your skin becomes irritated or sensitive after using Diprocel ointment, you should stop using it and tell your doctor.
- Contact your doctor if you experience blurred vision or other visual disturbances.
- If you think that you have developed a skin infection while using Diprocel ointment, you should tell your doctor as you may need to be given another type of medicine to use. If the infection does not improve, stop using Diprocel ointment and tell your doctor.

- Things you must not do

- Avoid getting the ointment into your eyes.
- Do not give Diprocel ointment to anyone else, even if they have the same symptoms or condition as you.
- Do not use Diprocel ointment more often than you should, on large areas of the body, for a long period of time, under bandages, plasters, or diapers, or more than prescribed, the chance of side effects increases.

- Things to be careful of

Use in children

If the ointment is used more often than it should, on large areas of the body, for a long period of time, or more than prescribed, it can affect some of your child's hormones. This may affect their growth and development.

Side effects

Like all medicines, Diprocel ointment can cause side effects, although not everybody gets them.

Most frequent but rare side effects reported are mild to moderate inflammation of the hair follicles.

Other side effects that have been reported include:

- Hives
- Redness of the skin
- Formation of blisters on the skin
- Itchiness of the skin

Side effects that have been reported following the use of topical corticosteroid include:

- Burning
- Irritation of the skin
- Dryness of the skin
- Excessive hair growth
- Acne
- Secondary skin infections
- Reduce pigmentation of the skin
- rashes around the mouth
- Allergic skin reaction
- Thinning of the skin
- Softening/breakdown of the skin
- Stretch marks
- Heat rash
- Blurred vision

Tell your doctor if you get any side effects. Side effects that may happen with inhaled or oral corticosteroids may also occur with corticosteroids used on the skin, especially 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 calling Tel: 03-78835549, or visiting the website npra.moh.gov.my [Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Storage and Disposal of Diprocel ointment

- Storage

- Keep out of reach and sight of children.
- Store below 30°C.
- Do not use this medicine after the expiry date which is stated on the label and carton after 'Use by'. The expiry date refers to the last day of that month.

- Disposal

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 it looks like

Smooth, uniform, white pearlescent ointment, free from foreign matter.

- Ingredients

Active ingredient:

Each gram of Diprocel ointment contains 0.64 mg betamethasone dipropionate (equivalent to 0.5 mg betamethasone)

Inactive ingredients:

Propylene glycol monostearate, propylene glycol, white wax and white petrolatum.

- MAL number:

MAL19870593AZ

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Manufacturer

Schering-Plough Labo N.V.,
Heist-op-den-Berg, Belgium under
authority of Schering-Plough
Corporation.

Product Registration Holder

Merck Sharp & Dohme (Malaysia) Sdn.
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