

PACKAGE LEAFLET: INFORMATION FOR THE USER

Dermodrin ointment

Active substance: diphenhydramine hydrochloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

What is in this leaflet

1. What Dermodrin ointment is and what it is used for
2. What you need to know before you use Dermodrin ointment
3. How to use Dermodrin ointment
4. Possible side effects
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1. What Dermodrin ointment is and what it is used for

Cooling antihistamine ointment for cutaneous use.

How it works

Diphenhydramine hydrochloride, the active substance of Dermodrin, is an antihistamine and antiallergic agent, an anti-itching agent and relieves pain in allergies and skin conditions.

Dermodrin ointment, as an oil-in-water emulsion, has a cooling effect.

Dermodrin ointment is intended for external use only.

The creamy, white, totally non-irritant and odourless preparation can be easily rubbed in and spread over the skin.

The effect sets in shortly after applying the ointment and lasts for 2-6 hours.

Therapeutic indications:

Dermodrin ointment is used to treat itching, local pain and hypersensitivity reactions of the skin in cases of

- allergies
- insect stings
- eczema, nettle rash, itchy wound edges and skin abrasions
- minor burns, sunburn
- itchy skin rash after sun exposure (sun allergy).

2. What you need to know before you use Dermodrin ointment

Do not use Dermodrin ointment

- if you are allergic to diphenhydramine hydrochloride, other antihistamines, peanuts or soya or any of the other ingredients of this medicine (listed in section 6),

- in newborn infants and children under 2 years of age
- on open wounds or mucous membranes, extensive skin changes such as inflamed and injured skin, especially in patients suffering from chickenpox, shingles or measles or in cases of skin blistering.

Warnings and precautions

Talk to your doctor or pharmacist before using Dermodrin ointment.

- If you expose treated skin areas to sunlight over prolonged periods, this may trigger possible hypersensitivity reactions to light.
- If no improvement occurs or your symptoms get worse, you must consult a doctor.
- Wash your hands after use, so that Dermodrin ointment does not come into contact with your eyes.
- Diphenhydramine should be used with special care if you have sleep apnoea (if you stop breathing in your sleep) [or if you have a known history of cot death in your family].

Dermodrin ointment is to be used with special care in elderly, debilitated or acutely ill patients.

Other medicines and Dermodrin ointment

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. After use of Dermodrin ointment, no interactions with other medicines have been observed to date.

Dermodrin ointment should not be used at the same time as other medicines containing diphenhydramine.

When used externally over large areas, interactions cannot be definitely ruled out. This particularly applies to the combined use of medicines containing diphenhydramine or so-called monoamine oxidase inhibitors (certain antidepressants or anti-Parkinson agents).

Atropine and tricyclic antidepressants can enhance certain properties of diphenhydramine hydrochloride; combined use with medicines that depress the central nervous system, such as psychotropic agents, sleeping pills, opioid painkillers, medicines for high blood pressure and alcohol, can mutually enhance their respective effects in an unpredictable manner.

Pregnancy and breast-feeding

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

Dermodrin ointment must not be used in the first 3 months of pregnancy. During the remainder of the pregnancy, Dermodrin should be used only after careful benefit/risk assessment by the doctor and after the individual dose has been established. Application over large areas must be avoided, especially on inflamed and injured skin.

The routine use of diphenhydramine in pregnancy is generally not recommended due to the lack of controlled clinical studies [this applies particularly to the last 2 weeks of pregnancy].

Dermodrin ointment must not be used during breast-feeding, as the active substance (diphenhydramine) passes into breast milk.

Driving and using machines

Dermodrin ointment has no or negligible influence on the ability to drive and use machines.

Dermodrin ointment contains

- 14.53% peanut oil. If you are allergic to peanuts or soya, do not use this medicinal product.
- methylhydroxybenzoate, which can cause mild irritation to the skin, eyes and mucous membranes.
- cetyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

3. How to use Dermodrin ointment

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

The recommended dose is

Adults and adolescents aged 12-18 years apply a ribbon of ointment 5-15 cm long (equivalent to 18-54 mg diphenhydramine) to the affected skin area 3 – 4 times daily, depending on the size of the site to be treated.

The daily dose of 300 mg diphenhydramine hydrochloride, equivalent to 15 g Dermodrin ointment, must not be exceeded. 300 mg is equivalent to 3/4 of a 20 g tube, 1/3 of a 50 g tube and 1/6 of a 100 g tube.

For *children aged 6 – 11 years*, a ribbon of ointment about 8-10 cm long is applied 3 – 4 times daily. The maximum daily dose of 150 mg diphenhydramine (equivalent to a 41 cm ribbon of ointment/day) must not be exceeded.

For *children aged 2 – 5 years*, a ribbon of ointment about 3 cm long is applied 2 – 3 times daily; the maximum daily dose of 37 mg diphenhydramine (equivalent to a 10 cm ribbon of ointment/day) must not be exceeded.

The duration of treatment should be as short as possible.

Dose recommendations for patients at risk

In elderly, debilitated and acutely ill patients, patients with severely impaired liver function or with severe kidney dysfunction, the dosage should be carefully adjusted to the symptoms.

If symptoms do not improve after two weeks of uninterrupted use, you must consult a doctor.

If you use more Dermodrin ointment than you should

No case of overdose with Dermodrin ointment has been reported to date.

If Dermodrin ointment has been accidentally swallowed, please contact a doctor immediately.

If you forget to use Dermodrin ointment

Do not use a double dose to make up for a forgotten dose.

If you stop using Dermodrin ointment

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Side effects can occur at the following frequencies:

-*Very common* ($\geq 1/10$)

-*Common* ($\geq 1/100$ to $< 1/10$)

-*Uncommon* ($\geq 1/1,000$ to $< 1/100$)

-*Rare* ($\geq 1/10,000$ to $< 1/1,000$)

-*Very rare* ($< 1/10,000$)

-*Not known* (cannot be estimated from the available data).

The following side effects may occur:

General disorders and administration site conditions, skin and subcutaneous tissue disorders

Uncommon: allergic skin reactions, contact dermatitis and increased sensitivity to sunlight may occur (avoid direct sun exposure), with itching, redness, blistering and swelling.

Rare: dry mouth.

Nervous system disorders

Rare: there have been reports of hypersensitivity reactions, tiredness and states of excitation (restlessness, anxiety and seizures), especially in children.

Renal and urinary disorders

Very rare: problems in urinating (passing water).

Reporting of side effects

If you get any side effects, talk to your <doctor> <or> <,> <pharmacist> <or nurse>. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the national reporting system:

Bundesamt für Sicherheit im Gesundheitswesen

(Federal Office for Safety in Health Care)

Traisengasse 5

1200 VIENNA

AUSTRIA

fax: + 43 (0)50 555 36207

website: <http://www.basg.gv.at/>

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dermodrin ointment

Keep this medicine out of the sight and reach of children.

Store in the original package in order to protect from light.

The shelf life after opening the container is 12 months.

Do not use this medicine after the expiry date, which is stated on the tube after <<Use by:>>. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Dermodrin ointment contains

- The active substance is: diphenhydramine hydrochloride
- 1 g ointment contains 20 mg diphenhydramine hydrochloride.
- The other ingredients are: methylhydroxybenzoate (0.15% g/g), peanut oil, bleached wax, cetyl alcohol, hard paraffin, white Vaseline, glycerol, Hostacerin T-3, polysorbate 80, isobornyl acetate, sodium hydroxide for pH adjustment, purified water.

What Dermodrin ointment looks like and contents of the pack

White, odourless ointment for application to the skin.

Pack sizes: tubes with 20 g, 50 g and 100 g, in a folded carton.

Marketing Authorisation Holder and Manufacturer

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