

PATIENT INFORMATION LEAFLET

DERMITON 10% lotion

For external use.

- **Active substance:** Each 1 ml lotion contains 100 mg crotamiton.
- **Excipients:** Isopropyl myristate, cetyl alcohol, stearic acid, glyceryl monostearate-PEG 100 stearate, propylene glycol, sorbic acid, cetostearyl alcohol, phenylethyl alcohol, vanilla-flavored, and deionized water.

Read this PATIENT INFORMATION LEAFLET carefully before you start using this medicine, because it contains important information for you.

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *When you go to a doctor or hospital while using this medicine, tell your doctor that you are receiving this medicine.*
- *Follow strictly what has written on this leaflet. Do not use **higher** or **lower** dose other than the recommended to you.*

What is in this leaflet:

1. *What DERMITON is and what is it used for?*
2. *Before you use DERMITON*
3. *How to use DERMITON?*
4. *Possible side effects*
5. *How to store DERMITON?*

1 .What DERMITON is and what is it used for?

- DERMITON is an externally used lotion containing crotamiton and is marketed in 100 ml glass bottles with spray head.
- DERMITON is used for relieving skin sensitivity and itchiness caused by sunburn, dry eczema, itchy skin inflammation (dermatitis), allergic rashes, itchy rash (urticaria) due to various reasons, varicella, insect bites and stings, nappy rash and itching and it is also indicated for treatment of scabies.

2 .Before you use DERMITON

DO NOT take DERMITON in the following cases

If,

- You are allergic (hypersensitive) to crotamiton or any of the other ingredients of the DERMITON
- You have a skin condition with exudative wound (acute exudative dermatoses)

Take special care with DERMITON in the following conditions

- If you are pregnant, you are breastfeeding or you have genital itching
- If it is to be used for children under 3 years of age

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Using DERMITON with food and drink:

There is no data for using of DERMITON with food and drinks.

Pregnancy

Ask your doctor or pharmacist for advice before using the medicine.

DERMITON is not recommended if you are pregnant.

If you notice that you are pregnant during treatment, please consult your doctor or pharmacist immediately.

Breast-feeding

Ask your doctor or pharmacist for advice before using the medicine.

DERMITON is not recommended during breast-feeding.

Driving and using machines

Any study for effects on driving and using machines of DERMITON has not performed.

Important information about some of the excipients of DERMITON

DERMITON contains cetyl alcohol and cetostearyl alcohol which may rarely cause local skin reactions (e.g. contact dermatitis, a condition occurred with contacting).

DERMITON contains propylene glycol which may cause skin irritation.

If you have been told by your doctor that you have an allergy to any of the ingredients of the DERMITON, contact your doctor before using this medicine.

Using with other medicines

There is no data for using of DERMITON with other medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine.

3. How to use DERMITON?

- **Instructions for appropriate method and dose/frequency of administration:**

Itching:

Apply to the affected area 2-3 times daily. DERMITON will provide relief from irritation for 6-10 hours after each application.

Scabies:

After you have taken a warm bath, dry thoroughly your skin and apply DERMITON into the entire body surface (excluding the face and scalp) until no traces of the preparation remain visible on the surface. The application should be repeated once daily, preferably in towards evening, for a total of 3-5 days.

Depending on the response, special attention should be paid to sites (e.g. interdigital spaces, wrists, axillae and genitalia) that are particularly susceptible to the proliferation of house dust mites (infestation by the mites). Cover the areas with pus formation with a dressing impregnated DERMITON. While the treatment is in progress you may take a bath shortly before the next application. After completion of the treatment, a cleansing bath should be taken followed by a change of bed linen and underclothing.

- **Route and method of administration:**

DERMITON is for external use only. Shake well before use.

It should not be used in or around the eyes since contact with the eyelids may give rise to conjunctival inflammation.

- **Different age groups:**

Use in children:

DERMITON can be used in children. There are no special dosage recommendations in the children.

Scabies:

DERMITON should not be applied more than once a day for children under 3 years of age.

Use in elderly:

There are no special recommendations in the elderly.

- **Special populations**

Kidney/Liver failure:

There are no special recommendations in patients with kidney/liver failure.

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

If you have used more DERMITON than you should:

If you may have used more DERMITON than you should, talk to a doctor or pharmacist.

If you forget to use DERMITON:

Do not use double dose to balance the missed doses.

Please continue to use the recommended dosage according to the later hours of normal use.

If you stop using DERMITON:

Not applicable.

4. Possible side effects

Like all medicines, DERMITON may cause side effects in some patients who are sensitive to the substances contained in DERMITON.

Side effects were listed as shown in the following categories:

Very common: may be seen at least 1 in 10 patients.

Common: may be seen less than 1 in 10 patients but 1 in 100 patients or more than 1.

Uncommon: may be seen less than 1 in 100 patients but more than 1 in 1.000 patients or more than 1.

Rare: may be seen less than 1 in 1.000 patients but more than 1 in 10.000 patients or more than 1.

Very rare: may be seen less than 1 in 10.000 patients.

Unknown: it cannot be estimated from the available data.

If you notice any of the following, please tell your doctor:

Uncommon (may be seen less than 1 in 100 patients but more than 1 in 1.000 patients):

- Itching

Rare (may be seen less than 1 in 1.000 patients):

- Contact dermatitis, hypersensitivity (rash, eczema, skin redness (erythema), skin irritation, skin reactions with deeper and widespread edema of the hands and feet, lips, genital organs and soft-tissue in the eyelids (such as angioedema)

These represent mild side effects of DERMITON.

These side effects disappear when the dosage is reduced or treatment is stopped.

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

5 . How to store DERMITON?

Keep out of the sight and reach of children and store in the original package.

Store at room temperature below 25°C.

Use in accordance with the expiry date.

Do not use DERMITON after the expiry date on packaging or bottle.

Do not use DERMITON if you notice any damage on product and/or packaging.

Marketing authorization holder:

Berko İlaç ve Kimya Sanayi A.Ş.

Yenişehir Mah. Özgür Sok. No: 16-18 Ataşehir/İstanbul-Turkey

+90 216 456 65 70 (Pbx)

+90 216 456 65 79 (Fax)

info@berko.com.tr

Manufacturer:

Berko İlaç ve Kimya Sanayi A.Ş.

Adil Mah. Yörükler No: 2 Sultanbeyli/ İstanbul-Turkey

+90 216 592 33 00 (Pbx)

+90 216 592 00 62 (Fax)

This patient information leaflet was last approved on 14/07/2017.