SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT
DERMITON 10% lotion, 100 ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each 1 ml lotion contains

Active substance:

Crotamiton	100.0 mg

Excipients:

Cetyl alcohol	20.0 mg
Cetostearyl alcohol	10.0 mg
Propylene glycol	100.0 mg

For excipients, see 6.1.

3. PHARMACEUTICAL FORM
Topical lotion
Almost white lotion.

4. CLINICAL PROPERTIES
4.1. Therapeutic indications
DERMİTON is indicated for the relief of itching and skin irritation caused by, for example sunburn, dry eczema, itchy dermatitis, allergic rashes, nettle rash, chickenpox, insect bites and stings, heat rashes and personal itching.

It is also indicated for treatment of the scabies.

4.2. Posology and method of administration
Posology/frequency of administration and duration:
It is used as follows unless otherwise recommended by a physician;
Itching:
Apply to the affected area 2-3 times daily. DERMİTON will provide relief from irritation for 6-10 hours after each application.

Scabies:
After the patient has taken a warm bath, the skin should be well dried and DERMİTON, rubbed into the entire body surface (excluding the face and scalp) until no traces of the preparation remains 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 that are particularly susceptible to infestation by the mites (e.g. interdigital spaces, wrists, axillae and genitalia). Areas where there is pus formation should be covered with a dressing impregnated DERMİTON. While the treatment is in progress the patient 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.

Additional information on special populations
Renal/Hepatic failure:
No data available.

Pediatric population
Itching:
DERMİTON can be used in children. There are no special dosage recommendations in the children.

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

Geriatric population
There are no special dosage recommendations in the elderly.

4.3. Contraindications
It should be not used in patients with hypersensitivity to the active substance or to any of the excipients in composition of the DERMİTON.

It is contraindicated in acute exudative dermatoses.

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

4.4. Special warnings and precautions for use
DERMİTON can be used in children. However for children under 3 years of age, the physician should be consulted.

For external use only. Shake well before use.

It should not be used around the eyes or on broken skin, in exudative wounds or in case of the hypersensitivity to any of the ingredients.

DERMİTON should only be used in pregnancy, breast feeding or for genital itching physician or pharmacist should be consulted.

DERMITON contains cetyl alcohol and cetostearyl alcohol which may rarely cause local skin reactions (e.g. contact dermatitis).

DERMITON contains propylene glycol which may cause skin irritation.

4.5. Interaction with other medicinal products and other forms of interaction
No data available.

4.6. Pregnancy and lactation
General recommendation:
Pregnancy category is C.

Women with Childbearing Potential/Birth control (Contraception)
There are no adequate data for the usage in women with childbearing potential.

Pregnancy
Animal studies are insufficient with respect to effects on pregnancy/ and-or/embryonic / fetal development/ and-or postnatal development. The potential risk for humans is unknown.

Therefore, DERMİTON is not recommended during pregnancy, especially in the first three months.

Lactation
It is not known whether the Crotamiton passes into breast milk. It should not be applied to the nipple area by nursing mothers.

Fertility
The effects on the reproductive ability have not been reported.

4.7. Effects on ability to drive and use machines
No data available.

4.8. Undesirable effects
The adverse reactions reported have been listed by the following frequency (very common (≥ 1/10); common (≥ 1/100 to< 1/10); uncommon (≥ 1/1.000 to < 1/100); rare (≥ 1/10.000 to < 1/1.000); very rare (< 1/10.000), not known (cannot be estimated from available data).

Uncommon: Itching
Rare: Contact dermatitis, hypersensitivity (like rash, eczema, erythema, skin irritation, angioedema)

Treatment should be discontinued if severe irritation occurs.

4.9. Overdose

DERMİTON is only for topical use. In cases of accidental ingestion nausea, vomiting and irritation of the buccal, oesophageal and gastric mucosa have been reported. In cases of ingestion in large quantities, there is no specific antidote. General measures to eliminate the drug and reduce its absorption should be undertaken. Symptomatic treatment should be administered as appropriate. Risk of methaemoglobinaemia exists and treatment with methylene blue may be considered.

5. PHARMACOLOGICAL PROPERTIES
5.1. Pharmacodynamic Properties
Pharmacotherapeutic group: Other antipruritics
ATC Code: D04AX
DERMİTON has a symptomatic action on pruritus and is an acaricide.

5.2. Pharmacokinetic properties
DERMİTON penetrates rapidly into human skin. Low but measurable concentrations of crotamiton are found in plasma, with a maximum level after 4-10 hours, declining rapidly thereafter.

5.3. Preclinical safety data
Crotamiton 10% Lotion administered dermally topically once daily under occlusive dressing for 3 months to rabbits was tolerated at doses of up to 250 mg/kg without signs of toxicity, apart from transient skin irritation. No sensitizing increase or photo-sensitizing increase has been observed in animal studies.

6. PHARMACEUTICAL PROPERTIES
6.1. List of excipients
Isopropyl myristate
Cetyl alcohol
Stearic acid
Glyceryl stearate –PEG 100 stearat
Propylene glycol
Sorbic acid
Cetostearyl alcohol
Phenylethyl alcohol
Vanilla cream essence
Deionized water

6.2. Incompatibilities
There is no evidence for any existing incompatibilities of DERMİTON with any drug or agent.

6.3. Shelf life
24 months

6.4. Special precautions for storage
Store at room temperature below 25ºC.

6.5. Nature and contents of container
DERMİTON, 100 ml is marketed in amber colored glass bottles with PP spray head closed with PP protective sheath.

6.6. Special precautions for disposal and other handling
Any unused product or waste material should be disposed of in accordance with “Directive on Control of Medical Waste” and “Directive on the Control of Packaging and Packaging Waste”.

7. MARKETING AUTHORIZATION HOLDER
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8. MARKETING AUTHORISATION NUMBER(S)

02.12.2013 – 254/70

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: 02.12.2013
Date of latest renewal:

10. DATE OF REVISION OF THE TEXT

14.07.2017