



## Nonsteroidal Alternative for Treating Pruritus

Help patients find relief from:

Pruritus

Scabies

## COPAY INFORMATION

ELIGIBLE PATIENTS  
PAY NO MORE THAN \$0  
FOR EACH PRESCRIPTION

Help Desk: 844-728-3479 \*Terms and conditions may apply.

**PROCESSOR:** Drexli

**BIN #:** 017290

**PCN #:** 55101202

**GROUP #:** X7540

**ID #:** 1001001

**PERSON CODE:** 01

## Crotan™ Lotion (Crotamiton, USP 10%)

237 gm | NDC: 0682-0051-10  
454 gm | NDC: 0682-0051-30

### INDICATIONS:

For eradication of scabies (*Sarcoptes scabiei*) and for symptomatic treatment of pruritic skin.

### CONTRAINDICATIONS:

Crotan lotion should not be applied topically to patients who develop a sensitivity or are allergic to it or who manifest a primary irritation response to topical medications.

### WARNINGS:

If severe irritation or sensitization develops, treatment with this product should be discontinued and appropriate therapy instituted.

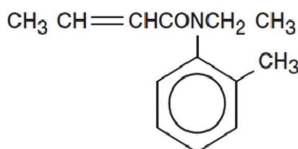
For full Prescribing Information, see attached Product Insert.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.

CROTAN- crotamiton lotion  
Marnel Pharmaceuticals, Inc.  
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**CROTAN LOTION  
FOR TOPICAL USE ONLY. NOT FOR OPHTHALMIC, ORAL  
OR INTRAVAGINAL USE.  
Rx ONLY**

CROTAN (crotramiton USP 10%) is a scabicide and antipruritic agent as a lotion for topical use only. Crotramiton is a colorless to slightly yellowish oil, having a faint amine-like odor. It is miscible with alcohol and with methanol. Crotramiton is a mixture of the cis and trans isomers. Its molecular weight is 203. 28. Crotramiton is -ethyl-N-(o-methyl-phenyl) 2-butenamide and its structural formula is:



CROTAN™ lotion contains crotramiton USP 10% (100mg/ml) in a creamy lotion base containing purified water, light mineral oil, propylene glycol, cetearyl alcohol (and) cetearth-20, cetyl alcohol, lanolin, benzyl alcohol, carbomer 971P, sodium hydroxide with citric acid (for pH adjustment).

**CLINICAL PHARMACOLOGY:** CROTAN lotion has scabicide and antipruritic actions. The mechanisms of these actions are not known. The pharmacokinetics of crotramiton and its degree of systemic absorption following topical application have not been determined.

**Geriatric Use:** Clinical studies with CROTAN (crotramiton USP) lotion did not include sufficient numbers of subjects aged 65 years and older to determine whether they respond differently than younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

**ADVERSE REACTIONS:** Primary irritation reactions such as dermatitis, pruritus and rash, and allergic sensitivity reactions have been reported in a few patients. To report SUSPECTED ADVERSE REACTIONS, contact Marnel Pharmaceuticals at 1-888-850-2905 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**OVERDOSAGE:** There is no specific information on the effect of overtreatment with repeated topical applications in humans. A death was reported but cause was not confirmed. Accidental oral ingestion may be accompanied by burning sensation in the mouth, irritation of the buccal, esophageal and gastric mucosa, nausea, vomiting, abdominal pain.

If accidental ingestion occurs, call your Poison Control Center.

**DOSE AND ADMINISTRATION:**

**SHAKE WELL BEFORE USE.**

*In Scabies:* Thoroughly massage into the skin of the whole body, from the chin down, paying particular attention to all folds and increases. A second application is advisable 24 hours later. Clothing and bed linen should be changed the next morning. A cleansing bath should be taken 48 hours after the last application.

*In Pruritus:* Massage gently into affected areas until medication is completely absorbed.

Repeat as needed.

**DIRECTIONS FOR PATIENTS WITH SCABIES:**

1. Take a routine bath or shower. Thoroughly massage CROTAN lotion into the skin from the chin to the toes including folds and creases.
2. Put CROTAN™ lotion under fingernails after trimming the fingernails short, because scabies are likely to remain there. A toothbrush can be used to apply the CROTAN™ lotion under the fingernails. Immediately after use, the toothbrush should be wrapped in paper and thrown away. Use of the brush in the mouth could lead to poisoning.
3. A second application is advisable 24 hours later.
4. Clothing and bed linen should be changed the next day. Contaminated clothing and bed linen may be dry-cleaned or washed in the hot cycle of the washing machine.
5. A cleansing bath should be taken 48 hours after the last application.

**INDICATIONS AND USAGE:** For eradication of scabies (*Sarcoptes scabiei*) and for symptomatic treatment of pruritic skin.

**CONTRAINDICATIONS:** CROTAN™ lotion should not be applied topically to patients who develop a sensitivity or are allergic to it or who manifest a primary irritation response to topical medications.

**WARNINGS:** If severe irritation or sensitization develops, treatment with this product should be discontinued and appropriate therapy instituted.

**PRECAUTIONS: General:** CROTAN™ lotion should not be applied in the eyes or mouth because it may cause irritation. It should not be applied to acutely inflamed skin or raw or weeping surfaces until acute inflammation has subsided.

**Information for Patients:** See "DIRECTIONS FOR PATIENTS WITH SCABIES."

**Drug Interactions:** None known.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long-term carcinogenicity studies in animals have not been conducted.

**Pregnancy (Category C):** Animal reproduction studies have not been conducted with CROTAN (crotramiton USP) lotion. It is also not known whether CROTAN can cause fetal harm when applied to a pregnant woman or can affect reproduction capacity. CROTAN™ should be given to a pregnant woman only if clearly needed.

**Pediatric Use:** Safety and effectiveness in children have not been established.

CROTAN (crotramiton USP) lotion, 10% is available in:

60 gm ( **NDC:** 0682-0051-20)

237 gm ( **NDC:** 0682-0051-10)

454 gm ( **NDC:** 0682-0051-30)

Rx ONLY

Mfd For:

Marnel Pharmaceuticals LLC  
Charleston, South Carolina USA  
888-850-2905  
Rev July 2021

**KEEP OUT OF REACH OF CHILDREN.**

**STORAGE:** Store 20° to 25°C (68 - 77°F). Excursions allowed between 15° and 30°C (59° and 86° F) [See USP Controlled Room Temperature].

**HOW TO WRITE  
FOR PRURITUS:**

**Crotan™ Lotion**

Apply a thin layer to the  
affected area 2 to 3 times daily.

10%

Dispense as written



Visit our website at:  
**FLEXDOSING.COM**

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