EURAX- crotamiton cream
Journey Medical Corporation

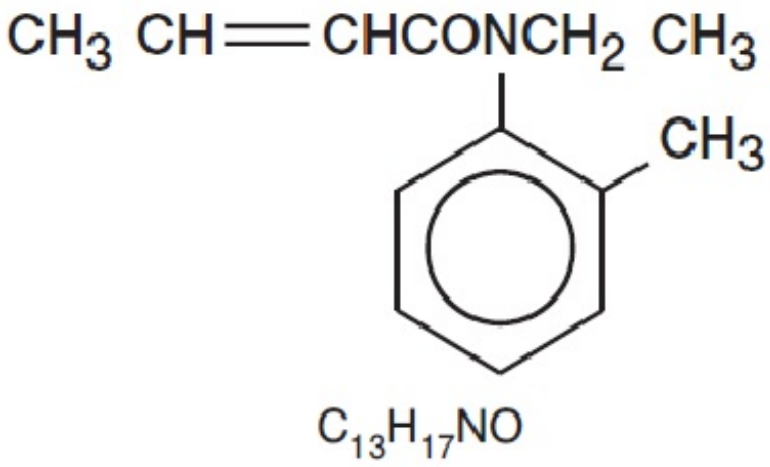
Eurax ®(crotamiton, USP)
Cream (10% w/w)

FOR TOPICAL USE ONLY
NOT FOR OPHTHALMIC, ORAL, OR INTRAVAGINAL USE

Rx only

DESCRIPTION

Eurax (crotamiton, USP) is a scabicidal and antipruritic agent available as a cream for topical use only. Eurax provides 10% (w/w) of the synthetic, crotamiton, USP, in a vanishing-cream base containing: carbomer homopolymer type B, cetyl alcohol, diazolidinyl urea, dimethicone, glyceryl monostearate, laureth-23, magnesium aluminum silicate, benzyl alcohol, petrolatum, propylene glycol, sodium hydroxide, steareth-2, and water. Crotamiton is N-ethyl-N-(*o*-methylphenyl)-2-butenamide and its structural formula is:



Crotamiton, USP is a colorless to slightly yellowish oil, having a faint amine-like odor. It is soluble with alcohol and with methanol. Crotamiton is a mixture of the *cis*and *trans*isomers. Its molecular weight is 203.28.

CLINICAL PHARMACOLOGY

Eurax has scabicidal and antipruritic actions. The mechanisms of these actions are not known. The pharmacokinetics of crotamiton and its degree of systemic absorption following topical application have not been determined.

INDICATIONS AND USAGE

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

skin.

CONTRAINDICATIONS

Do not apply Eurax topically to patients who develop a sensitivity or are allergic to it or who manifest a primary irritation response to topical medications.

WARNINGS

Discontinue treatment with this product if severe irritation or sensitization develops, and institute appropriate therapy.

PRECAUTIONS

General

Do not apply Eurax in the eyes or mouth because it may cause irritation. Do not apply on acutely inflamed skin or raw or weeping surfaces until the 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

Animal reproduction studies have not been conducted with Eurax. It is also not known whether Eurax can cause fetal harm when applied topically to a pregnant woman or can affect reproduction capacity. Eurax should be given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

Clinical studies with Eurax (crotamiton, USP) Cream 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.

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.

DOSAGE AND ADMINISTRATION

*In Scabies:*Thoroughly massage into the skin of the whole body from the chin down, paying particular attention to all folds and creases. A second application is advisable 24 hours later. Change clothing and bed linen the next morning. Take a cleansing bath 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 Eurax cream into the skin from the chin to the toes including folds and creases.
2. Put Eurax cream under fingernails after trimming the fingernails short, because scabies are very likely to remain there. A toothbrush can be used to apply the Eurax cream under the fingernails. Immediately after use, wrap the toothbrush in paper and throw it away. Use of the same brush in the mouth could lead to poisoning.
3. A second application is advisable 24 hours later.
4. A 60 gram tube is sufficient for two applications.
5. Change clothing and bed linen the next day. Dry clean contaminated clothing and bed linen, or wash in the hot cycle of the washing machine.
6. Take a cleansing bath 48 hours after the last application.

HOW SUPPLIED

Eurax ®(crotamiton, USP) Cream, 10% is a white to yellowish-white soft cream and supplied as:
60 g tube NDC 69489-311-60

Store at room temperature, 20˚C - 25˚C (68˚F - 77˚F); Excursions permitted: 15˚C - 30˚C (59˚F - 86˚F)
[See USP Controlled Room Temperature].

Keep out of reach of children.

To report SUSPECTED ADVERSE REACTIONS, contact Journey Medical

Corporation at 1-855-531-1859 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Manufactured for:
Journey Medical Corporation
Scottsdale, AZ 85258
www.JMCderm.com

EUR-P01-R00
Revised 12/2025

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

NDC 69489-311-60

eurax ®

(crotamiton, USP) **Cream (10% w/w)**

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Net Wt. 60 g

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EURAX

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Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69489-311
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
CROTAMITON (UNII: D6S4O4XD0H) (CROTAMITON - UNII:D6S4O4XD0H)	CROTAMITON	100 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)	
LAURETH-23 (UNII: N72LMW566G)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
STEARETH-2 (UNII: V56DFE46J5)	

GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69489-311-60	1 in 1 CARTON	03/16/2026	
1		60 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA006927	03/16/2026	

Labeler - Journey Medical Corporation (079640860)

Registrant - Journey Medical Corporation (079640860)

Establishment

Name	Address	ID/FEI	Business Operations
DPT Laboratories, Ltd		832224526	analysis(69489-311) , label(69489-311) , manufacture(69489-311) , pack(69489-311)

Revised: 12/2025 Journey Medical Corporation