Rx only

Eurax

(crotamiton USP)

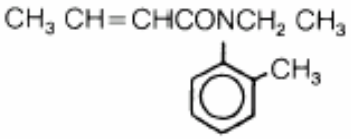
Lotion/Cream

FOR TOPICAL USE ONLY

NOT FOR OPHTHALMIIC, ORAL, OR INTRAVAGINAL USE

DESCRIPTION

Eurax (crotamiton USP) is a scabicidal and antipruritic agent available as a cream or lotion for topical use only. Eurax provides 10% (w/w) of the synthetic, crotamiton USP, in a vanishing-cream or emollient-lotion base containing: water, petrolatum, propylene glycol, steareth-2, cetyl alcohol, dimethicone, laureth-23, fragrance, magnesium aluminum silicate, carbomer-934, sodium hydroxide, diazolidinylurea, methylchloroisothiazolinone, methylisothiazolinone and magnesium nitrate. In addition, the cream contains glyceryl stearate. 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 miscible 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

Eurax 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

Eurax 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 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 (Category C)

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 children have not been established.

Geriatric Use

Clinical studies with Eurax (crotamiton USP) Lotion/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. 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.

LOTION: Shake well before using.

DIRECTIONS FOR PATIENTS WITH SCABIES:

1. Take a routine bath or shower. Thoroughly massage Eurax cream or lotion into the skin from the chin to the toes including folds and creases.

2. Put Eurax cream or lotion 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 or lotion under the fingernails. Immediately after use, the toothbrush should be wrapped in paper and thrown away. Use of the same brush in the mouth could lead to poisoning.
3. A second application is advisable 24 hours later.
4. This 60 gram tube or bottle is sufficient for two applications.
5. 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.

6. A cleansing bath should be taken 48 hours after the last application.

HOW SUPPLIED

Eurax (crotamiton USP)

Cream: 60g tubes (NDC 0072-2103-60; NSN 6505-00-116-0200).

Lotion: 60g (2 oz.) bottles (NDC 0072-2203-60, NSN 6505-01-153- 4423).
454g (16 oz.) bottles (NDC 0072-2203-16).
SHAKE WELL before using.

Store at room temperature.

Keep out of reach of children.

Westwood-Squibb Pharmaceuticals, Inc.
A Bristol-Myers Squibb Company
Princeton, NJ 08543 USA

Insert code TBD

Revised TBD