EURAX- crotamiton cream
EURAX- crotamiton lotion
Ranbaxy Laboratories Inc.

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Eurax® (crotamiton, USP)
Lotion/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 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: carbomer-934, cetyl alcohol, diazolidinylurea, dimethicone, fragrance, laureth-23, magnesium aluminum silicate, magnesium nitrate, methylchloroisothiazolinone, methylisothiazolinone, petrolatum, propylene glycol, sodium hydroxide, steareth-2, and water. In addition, the cream contains glyceryl stearate.

Crotamiton is N-ethyl-N-(o-methylphenyl)-2-butenamide and its structural formula is:

\[
\begin{align*}
\text{CH}_3 & \quad \text{CH} = \quad \text{CHCONCH}_2 \quad \text{CH}_3 \\
\text{C}_3\text{H}_7\text{NO} & \\
\end{align*}
\]

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 and Mutagenesis and 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 pediatric patients 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:

- 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.
- 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.
- A second application is advisable 24 hours later.
- A 60 gram tube or bottle is sufficient for two applications.
- 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.
- A cleansing bath should be taken 48 hours after the last application

HOW SUPPLIED

Eurax® (crotamiton, USP) Cream, 10% is a white to yellowish-white soft cream with a perfumed characteristic odor and supplied as:
60 g tubes NDC 10631-091-60 (NSN 6505-00-116-0200)

Eurax® (crotamiton, USP) Lotion, 10% is a white to yellowish-white lotion having a characteristic perfumed odor and supplied as:
60 g (2 oz.) bottle NDC 10631-092-60 (NSN 6505-01-153-4423)
454 g (16 oz.) bottle NDC 10631-092-16

SHAKE WELL before using.

Store at room temperature.

Keep out of reach of children.

To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

RANBAXY

Jacksonville, FL 32257 USA
129845
September 2012

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

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

Store at room temperature.
Keep out of reach of children.
For external use only.
Directions for Use:
See package insert.

Contains: 10% (w/w) crotamiton plus carbomer-934, cetyl alcohol, diazolidinylurea, dimethicone, fragrance, glyceryl stearate, laureth-23, magnesium aluminum silicate, magnesium nitrate, methylchloroisothiazolinone, methylisothiazolinone, petrolatum, propylene glycol, sodium hydroxide, steareth-2, and water.

NET WT. 60 g

Warning: This cream should not be used on acutely inflamed skin, raw, weeping surfaces, or in the eyes or mouth.

Lot Code and Expiration Date on Crimp.
NSN 6505-00-115-0200

RANBAXY
Jacksonville, FL 32257 USA

106219 0912

Eurax Cream 60 g Tube
Eurax Cream 60 g Tube
Eurax Cream 60 g Tube
Eurax Cream 60 g Carton

Eurax Lotion
### Product Information

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<thead>
<tr>
<th>Product Type</th>
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<tr>
<td>Route of Administration</td>
<td>TOPICAL</td>
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<tr>
<td>Item Code (Source)</td>
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### Active Ingredient/Active Moiety

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<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
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<tbody>
<tr>
<td>CROTAMITON (UNII: D6S4O4XD0H) (CROTAMITON - UNII: D6S4O4XD0H)</td>
<td>CROTAMITON</td>
<td>100 mg in 1 g</td>
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### Inactive Ingredients

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<thead>
<tr>
<th>Ingredient Name</th>
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<tr>
<td>CETYL ALCOHOL (UNII: 936JS76JCN)</td>
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<tr>
<td>DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)</td>
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<tr>
<td>CARBOXYMETHYL HOMOPOLYMER TYPE B (ALLYL SUCROSE CROSSLINKED) (UNII: Z135WT9208)</td>
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<tr>
<td>LAURETH-23 (UNII: N72LMW566G)</td>
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MAGNESIUM NITRATE (UNII: 77CBG3UN78)
METHYLCHLOROISOTHIAZOLINONE (UNII: DEL7T5QRPN)
STEARETH-2 (UNII: V56DFE46J5)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
DIMETHICONE (UNII: 92RU3N3Y1O)
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)
PETROLATUM (UNII: 4T6H12BN9U)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
SODIUM HYDROXIDE (UNII: 55X04QC32I)
WATER (UNII: 059QF0KOOR)

### Packaging
<table>
<thead>
<tr>
<th>#</th>
<th>Item Code</th>
<th>Package Description</th>
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<th>Marketing End Date</th>
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<td>1 in 1 CARTON</td>
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### Marketing Information

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### EURAX

crotamiton lotion

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## Labeler - Ranbaxy Laboratories Inc. (169932519)

## Registrant - Ranbaxy Laboratories Inc. (169932519)

## Establishment

<table>
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<th>Name</th>
<th>Address</th>
<th>ID/FEI</th>
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<tr>
<td>DPT Laboratories, Ltd</td>
<td>832224526</td>
<td>832224526</td>
<td>MANUFACTURE(10631-091, 10631-092), PACK(10631-091, 10631-092)</td>
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Revised: 1/2015