Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Eurax 10% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Crotamiton 10% w/w.

Excipients with known effect:

Methyl Parahydroxybenzoate (E218) 0.150 %w/w
Stearyl Alcohol 0.750 %w/w
Perfume (containing benzyl benzoate) < 0.125 % w/w

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Cream.
A white to cream coloured cream, giving a homogeneous smear, apart from trapped air bubbles; odour characteristic of perfume.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an antipruritic and sarcopticide for use in the management of pruritus of any aetiology and in the treatment of scabies.

4.2 Posology and method of administration

Pruritus
Adults (including the elderly):
Apply to the affected area 2 to 3 times daily. Eurax will provide relief from irritation for 6 to 10 hours after each application. There are no special dosage recommendations in the elderly.

Paediatric population:
Eurax Cream can be used in children. However for children under three years of age, usage should only be under medical supervision and it should not be applied more than once a day.

Scabies
Adults (including the elderly):

After a thorough bath, Eurax should be applied to all areas below the chin with particular attention to interdigital areas. It is advisable to repeat the treatment 24 hours later. A bath should be taken a day after with a change of clothes and bedding. All contacts should be treated simultaneously in scabatic patients.

There are no special dosage recommendations in the elderly.

Paediatric population:
Eurax Cream can be used in children. However for children under three years of age usage should only be under medical supervision and it should not be applied more than once a day.

Method of administration: For cutaneous use.

4.3 Contraindications

Acute exudative dermatoses.

Hypersensitivity to the active substance or to any of the excipients (see section 6.1, List of excipients).

4.4 Special warnings and precautions for use

If symptoms persist consult the doctor.

Eurax can be used for children. However for children under three years of age, usage should only be under medical supervision. For external use only.

Should not be used in buccal mucosa and in or around the eyes since contact with the eyelids may give rise to conjunctival inflammation. In case of accidental contact with the eyes, or buccal mucosa rinse thoroughly with running water.

Should not be applied in the presence of exudative wounds, acute eczema, broken skin, or very inflamed skin. In the presence of eczematous scabies, eczema should be treated before the scabies (see section 4.3).

Eurax cream contains stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis) and methyl hydroxybenzoate which may cause allergic reactions (possibly delayed).

Eurax cream should only be used in pregnancy, breast feeding or genital itching under medical supervision.

4.5 Interaction with other medicinal products and other forms of interactions

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no controlled studies of Eurax Cream in human pregnancy.
Eurax Cream is not recommended during pregnancy, especially in the first three months.

Breastfeeding
It is not known whether the active substance of Eurax Cream passes into breast milk after topical administration. Therefore mothers should not use Eurax Cream whilst breastfeeding unless directed by a physician.
If Eurax Cream is used during breastfeeding it should not be applied to the nipple area.

Fertility
No data is available on the potential effects of crotamiton on fertility.

4.7 Effects on ability to drive and use machines

Eurax Cream has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

The most commonly reported adverse reaction during treatment is pruritus. Contact dermatitis and hypersensitivity reactions like rash, eczema, erythema, skin irritation and angioedema may occur rarely.

Use near the eyes may produce inflammation of the conjunctiva.

Tabulated list of adverse reactions

Adverse reactions are listed below by system organ class and by frequency. Frequencies are defined as: 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) and very rare (<1/10,000), or not known (cannot be estimate from available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Skin and subcutaneous tissue disorders:
Uncommon: pruritus
Rare: contact dermatitis, hypersensitivity (like rash, eczema, erythema, skin irritation, angioedema)

Treatment should be discontinued if severe irritation occurs.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL -Dublin2; Tel: +353 1 6764971; Fax: + 353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Symptoms

In cases of accidental ingestion, acute intoxication symptoms may be observed such as nausea, vomiting and irritation of the buccal, esophageal and gastric mucosa. Rare cases of loss of consciousness and seizure were reported. General measures to eliminate the drug and reduce its absorption should be undertaken.
Although very rare, risk of methaemoglobinemia exists in case of accidental ingestion as well as in case of excessive cutaneous absorption.

Management

The symptoms usually disappear following the discontinuation of the drug, but in severe cases treatment with methyleneblue may be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: D04AX Other antipruritics and P03AX and other ectoparasiticides, incl. scabicides (ATC code P03AX).

Crotamiton has asymptomatic action on pruritus and is an acaricide. As an acaricide agent, crotamiton is effective on the motor system of the mites by inducing irreversible cessation of spontaneous movements.
Eurax Cream will provide relief from irritation for 6 to 10 hours after each application. Crotamiton has a bacteriostatic action against staphylococci and streptococci, which may be favourable for skin infections in serious cases of scabies.

5.2 Pharmacokinetic properties

Cutaneous application of Eurax Cream shows that crotamiton penetrates rapidly into the skin and remains there for less than 24 hours. The active substance is consistently released into the blood from where it is rapidly eliminated.

5.3 Preclinical safety data

Preclinical data do not show teratogenic nor genotoxic risk for crotamiton. Eurax Cream, a crotamiton containing cream, administered topically once daily for 3 months to rabbits was tolerated at doses of up to 200 mg/kg without signs of toxicity, apart from transient skin irritation. No sensitising or photo-sensitising potential has been observed in animal studies.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl Parahydroxybenzoate (E218)
Phenylethyl Alcohol
Glycerol
Trolamine (Triethanolamine)
Sodium Laurilsulfate
Ethylene Glycol Monopalmitostearate
Stearyl Alcohol
Concentrated Ammonia Solution
Stearic Acid
Hard Paraffin
White Beeswax
Perfume Givaudan No 45 (containing benzyl benzoate)
Purified Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Internally lacquered aluminium tubes with an inner coating made of epoxy-phenol resin lacquer closed with a polyethylene screw cap in a cardboard carton.

Pack sizes: 30g and 100g

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Clonmel Healthcare Ltd

Waterford Road
Clonmel
Co. Tipperary
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0126/325/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1 April 1978

Date of last renewal: 11 April 2008

10 DATE OF REVISION OF THE TEXT

November 2019