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: Methyl parahydroxybenzoate (E218) and stearyl alcohol

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream

Product imported from the UK:
A white to cream coloured cream, giving a homogenous 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

Apply to the affected area 2 to 3 times daily. Eurax will provide relief from irritation for 6-10 hours after each application. Eurax can be used in children. There are no special dosage recommendations in the elderly.

Scabies

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.

Method of administration: For cutaneous use.

4.3 Contraindications

Use in patients hypersensitive to any of the ingredients or suffering from acute exudative dermatoses.

4.4 Special warnings and precautions for use

If symptoms persist consult the doctor.

Eurax can be used for children, although it is advised that you consult your doctor before use on infants.

For external use only.

Eurax should not be used near the eyes or on broken skin, or for weeping skin conditions.

Consult your doctor before using Eurax if you are pregnant or breast feeding.

If you suffer from genital itching, consult your doctor or pharmacist before using Eurax.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, pregnancy and lactation

There is no evidence of risk during pregnancy. When breast feeding, application should not be made to the nipples.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

Use near the eyes may produce inflammation of conjunctiva. Local irritation of skin may occur.

4.9 Overdose

Symptomatic treatment.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

None stated.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Sodium laurilsulfate
Ethylene glycol monopalmitostearate
Concentrated ammonia solution
Phenylethyl alcohol
Glycerol
Triethanolamine
Stearyl alcohol
Stearic acid
Hard paraffin
White beeswax
Perfume

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the tube and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

Overlabelled tube in an overlabelled carton.
Pack size: 30g

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 PARALLEL PRODUCT AUTHORISATION HOLDER

G & A Licensing Ltd
Ballymurray
Co. Roscommon
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 1447/68/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12th November 2010

10 DATE OF REVISION OF THE TEXT