

# **Itch-Soothe**

**Crotamiton 10% w/w**

## **Presentation**

Itch-Soothe is a white opaque, non-greasy, non-perfumed cream with characteristic faint amine-like odour of crotamiton.

## **Uses**

### ***Actions***

Itch-Soothe Cream has a symptomatic action on pruritus and is an acaricide.

### ***Pharmacokinetics***

Itch-Soothe Cream penetrates rapidly into human skin. Low but measurable concentrations of crotamiton are found in plasma, with a maximum level after 4 - 10 hours, declining rapidly thereafter.

### ***Indications***

Itch-Soothe is used for the relief of itching and skin irritation caused by, for example, sunburn, dry eczema, itchy dermatitis, allergic rashes, hives, nettle rash, chickenpox, insect bites and stings and heat rashes.

Itch-Soothe is also used for the treatment of scabies.

## **Dosage and Administration**

### ***Pruritus***

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

### ***Scabies***

Adults (including the elderly):

Apply once daily, preferably in the evening, for 3-5 days.

After taking a warm bath, dry the skin well and rub Itch-Soothe Cream into the whole body (excluding the face and scalp) until no traces of the preparation remain visible on the surface.

Special attention should be paid to sites that are particularly susceptible to infestation by the mites (e.g. interdigital spaces, wrists, axillae and genitalia). Areas where there is pus formation should be covered with a dressing impregnated with Itch-Soothe Cream.

Itch-Soothe Cream should not be used in or around the eyes since contact with the eyelids may cause conjunctival inflammation.

In children under three years of age Itch-Soothe Cream should not be applied more than once a day. There are no special dosage recommendations in the elderly.

## **Contraindications**

Acute exudative dermatoses.

Hypersensitivity to any of the ingredients.

## **Warnings and Precautions**

For external use only.

Do not use in or around the eyes, on broken skin, for weeping skin conditions or if you are sensitive to any of the ingredients.

### ***Use during Pregnancy and Lactation***

Class B2. Medicines which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed.

Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of fetal damage.

Itch-Soothe Cream should be used only in cases where the health benefit outweighs the potential risk associated with the treatment.

It is not known whether crotamiton passes into the breast milk. Nursing mothers should avoid applying Itch-Soothe Cream in the area of the nipples.

### ***Effects on ability to drive and use machines***

No known effects.

## **Adverse Effects**

Occasionally irritation of the skin or contact allergy may occur. In such cases the preparation should be discontinued.

## **Interactions**

No known interactions.

## **Overdosage**

Itch-Soothe Cream is for topical application only and the overdosage is highly unlikely to occur. Nausea, vomiting and irritation of the buccal, oesophageal and gastric mucosa have been reported in cases where large quantities of crotamiton have been taken. There is no specific antidote and general measures to eliminate the drug and reduce its absorption should be undertaken in a case of overdose. Symptomatic treatment should be administered as appropriate. A risk of methaemoglobinaemia exists, which may be treated with methylene blue.

## **Pharmaceutical Precautions**

Store below 30 °C.

## **Medicines Classification**

General sale medicine.

## **Further Information**

Itch-Soothe Cream contains the following inactive ingredients: carbomer 940, glycerol, methyl hydroxybenzoate, propyl hydroxybenzoate, polawax GP 200, Triethanolamine and purified water.

## **Package Quantities**

Tube containing 20 g of the product.

## **Name and Address**

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## **Date of Preparation**

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