Professional Information

SCHEDULING STATUS S2

PROPRIETARY NAME (AND DOSAGE FORM):

DEMAZIN ITCH RELIEF

COMPOSITION:

Each 100 g of cream contains:

Mepyramine Maleate	2 g
Methylhydroxybenzoate	0,16 % *m/m*
Propylhydroxybenzoate	0,02 % *m/m*

Contains no TARTRAZINE.

Contains Sodium metabisulphite 0,1 % *m/m*

PHARMACOLOGICAL CLASSIFICATION:

A 13.4 Antipruritics (relieving itching)

PHARMACOLOGICAL ACTION:

Histamine H1 receptor antagonists compete reversibly with histamine for H1 receptor sites on effector cells. They suppress those symptoms due to histamine release.

DEMAZIN ITCH RELIEF has the actions and uses of antihistamine (medicine used to prevent or relieve symptoms of some types of allergies) drugs.

INDICATIONS:

DEMAZIN ITCH RELIEF is employed locally for allergic (unusual sensitisation) and pruritic (itching) skin disorders or for the symptomatic relief of hypersensitivity reactions. It is also employed locally for insect bites or stings.

CONTRA-INDICATIONS:

Hypersensitivity to any of the ingredients. Cross sensitivity to other antihistamines.

Pregnancy - Safety in pregnancy has not been established.

DEMAZIN ITCH RELIEF should not be used for acute vesicular (severe blister) and exudative dermatoses (fluid eruptions from skin).

DOSAGE AND DIRECTIONS FOR USE:

Apply to affected area two to three times a day.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Local application of DEMAZIN ITCH RELIEF carries a risk of sensitisation but dermatitis (inflammation of the skin) may also result.

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT:

For external use only

IDENTIFICATION:

Pale green cream with a pleasant aromatic odour

PRESENTATION:

25 g tubes and 500 g white or amber ointment jars.

STORAGE INSTRUCTIONS:

Store in a cool place, below 25 °C.

KEEP OUT OF REACH OF CHILDREN

REGISTRATON NUMBER:

G 1881(Act 101/1965)

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

iNova Pharmaceuticals (Pty) Ltd

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