**PACKAGE INSERT**

# DEMAZIN®
## ITCH RELIEF

**SCHEDULING STATUS:**

S2

**PROPRIETARY NAME (AND DOSAGE FORM):**

**DEMAZIN ITCH RELIEF**

**COMPOSITION:**

Each 100 g cream contains: Mepyramine maleate 2 g

Preservatives: 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**

**REGISTRATION NUMBER:**

G 1881 (Act 101/1965)

**NAME AND BUSINESS ADDRESS OF THE APPLICANT:**

iNova Pharmaceuticals (Pty) Ltd, 15E Riley Road, Bedfordview, 2007.

**DATE OF PUBLICATION OF THIS PACKAGE INSERT:**

March 1973

A9981

*APPROVED*
*By Praenisha at 1:51 pm, Apr 03, 2025*

**VOUBILJET**

# DEMAZIN®
## ITCH RELIEF

**SKEDULERINGSTATUS:**

S2

**EIENDOMSNAAM (EN DOSEERVORM):**

**DEMAZIN ITCH RELIEF**

**SAMESTELLING:**

Elke 100 g room bevat: Mepiramien maleaat 2 g

Preserverrmiddels: Metielhidroksibensoaat 0,16 % *m/m*, propielhidroksibensoaat 0,02 % *m/m*

Bevat geen tartrasien.

Bevat natriummetabisulfiet 0, 1 % *m/m*

**FARMAKOLOGIESE KLASSIFIKASIE:**

A 13.4 Antipruritiese middels (wat jeug verlig)

**FARMAKOLOGIESE WERKING:**

Histamien H1 reseptor antagoniste kompeteer omkeerbaar met histamien vir H1 reseptorliggings op effektorselle. Hulle onderdruk die simptome a.g.v. histamienvrystelling.

**DEMAZIN ITCH RELIEF** het die werking en behandeling van antihistamien (voorkoming of verligting van simptome geassosieer met party tipes allergiee) middels.

**INDIKASIES:**

**DEMAZIN ITCH RELIEF** is gebruik vir die plaaslike werking op allergies (ongewone sensitiwiteit) en prurities (jeuk) velaandoenings of vir die simptomatiese verligting van hipersensitiwiteits reaksies. Dit word ook lokaal gebruik vir insekbyt en steek wonde.

**KONTRA-INDIKASIES:**

Hipersensitiwiteit vir enigeen van die bestanddele. Kruissensitiwiteit vir ander antihistamienes.

Swangerskap - veiligheid tydens swangerskap is nog nie bevestig nie.

**DEMAZIN ITCH RELIEF** is nie aangedui vir akuut vesikuler (hewige blasieverwekte) en eksudatiewe dermatose \rloeistowwe uitbarsting van die vel).

**DOSIS EN GEBRUIKSAANWYSINGS:**

Aansmeer tot aangetaste dele twee tot drie maal per dag.

**NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:**

Plaaslike aansmeering van **DEMAZIN ITCH RELIEF** dra 'n groot risiko sensitisering (gevoeligmaking) maar dermatitis (velontsteking) kan ook voorkom.

**BEKENDE SIMPTOMSE VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING**

**DAARVAN:**

Alleen vir uitwendige gebruik.

**IDENTIFIKASIE:**

Vaal, groen room met 'n aangename aromaties geur.

**AANBIEDING:**

25 g Buise en 500 g wit of amberkleurige salf potjies.

**BERGINGSINSTRUKSIES:**

Bewaar op 'n koel plek, benede 25 °C.

**HOU BUITE BEREIK VAN KINDERS.**

**REGISTRASIENOMMER:**

G 1881 (WET 101/1965)

**NAAM EN BESIGHEIDSADRES VAN APPLIKANT:**

iNova Pharmaceuticals (Edms) Bpk, Rileyweg 15E, Bedfordview, 2007

**DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:**

Maart 1973

***APPROVED***
***By Praenisha at 1:51 pm, Apr 03, 2025***
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EST. 1964

**REPRO**

**Date:** 02 April 2025
**Operator:** Jacky Pistorius
**Customer:** Inova
**Product Name:** Demazin Itch Relief Pl

**Product Code:** A9981
**Dimensions:** 100 x 210 mm
**Fold:** 100 x 26 mm
**Colours: (1)** Black
**Pharmacode:** --
**Stock:** 50 gsm
**Proof Status** 1st (First)
**Proof read by:**

**Reset:** ☐ **Alterations:** ☐ **Disk/Possie:** ☑

**No alterations – proceed as soon as possible** ☐

**Note alterations – Further proof is required** ☐

**PLEASE CHECK CAREFULLY.**

**Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.**

**Signature:** ..... **Date:** .....

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***By Praenisha at 1:51 pm, Apr 03, 2025***