

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Histergan Cream
Boots Bite, Sting & Itch Relief 2% w/w Cream
Wasp-Eze Insect Bites, Stings & Allergy Relief 2% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Diphenhydramine Hydrochloride BP 2% w/w

Excipient with known effect:

Propyl Hydroxybenzoate

3 PHARMACEUTICAL FORM

Topical Cream

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of allergic conditions e.g.:-
Urticaria, pruritus, allergic rashes, stings and insect bites.

4.2 Posology and method of administration

Posology

Apply sparingly and infrequently (maximum twice daily) to the affected area. Short term treatment only - not more than three days.

Histergan Cream should not be used in children under six years.

Method of administration

Topical

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1

Known sensitivity to anti-histamines and benzoates. Do not apply to mucous membranes, eczematous conditions or where the skin is extensively broken or denuded, or in acute vesicular or exudative dermatoses. Do not use with any other product containing the same active ingredient.

4.4 Special warnings and precautions for use

Apply sparingly. Avoid prolonged use or repeated applications especially to large areas. If burning or rash develops, or if the condition persists, medical advice should be sought immediately. If necessary remove by washing with soap and water. Wash hands after use, unless they are being treated

Parahydroxybenzoates may cause allergic reactions (possible delayed).

4.5. Interaction with Other Medicinal Products and Other Forms of Interaction

None recorded.

4.6 Fertility, pregnancy and lactation

Considered safe in the recommended dose.

4.7 Effects on ability to drive and use machines

Has no influence on the ability to drive or operate machinery

4.8 Undesirable effects

May give rise to sensitisation reaction and photosensitivity. Rarely eczematous reactions have been reported, if this occurs, treatment should be discontinued.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation 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 the Yellow Card scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9. Overdose

Accidental ingestion or excessive absorption may lead to dose related signs of diphenhydramine toxicity which includes drowsiness and sedation.

Treatment is by gastric lavage and aspiration. In cases of acute poisoning, activated charcoal may be useful.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antipruritics, Incl. Antihistamines, Anesthetics.
Anithistamines for topical use
ATC.Code: D04AA

Diphenhydramine applied externally has anti-histaminic activity in conditions induced by allergic stimuli.

5.2. Pharmacokinetic Properties

Diphenhydramine is a histamine H₁ receptor antagonist.
External applications to largely intact skin results in minimal systemic absorption.

5.3. Preclinical Safety Data

None stated

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propyl Hydroxybenzoate, Liquid Paraffin, Emulsifying Wax, Deionised Water.

6.2. Incompatibilities

Not applicable.

6.3. Shelf Life

36 months

6.4 Special precautions for storage

Store below 25°C

6.5. Nature and Contents of Container

Tube 25g.

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Norma Chemicals Ltd.
51-53 Stert Street
Abingdon
Oxfordshire OX14 3JF
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 00386/5000R

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

4 December 1989 / 13 June 1995

10 DATE OF REVISION OF THE TEXT

06/11/2025