SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Fenistil 0,1% w/w Gel

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g of gel contains 1 mg of dimetindene maleate.

Excipients with known effect: Each 1 g of gel contains 150 mg propylene glycol and 0,1 mg benzalkonium chloride.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Odourless and colourless gel.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Relief from itching due to limited and mild symptoms of urticaria, demographism and dermatitis from natural causes such as insect or jellyfish bites or contact with plants and from pruritus associated with sunburn and superficial burns.

4.2 Posology and method of administration

Posology

Apply small quantity of gel 2-4 times a day to affected area of the skin.
Maximum duration of use: If no improvement is seen after 7 days of gel use, the patient should consult the physician.

Special use instructions

In case of very severe urticaria events or extensive skin lesions, doctor's or pharmacist's advice should be asked for the topical application of Fenistil to be supplemented by a systemic therapy with an oral form of antihistamine.

Paediatric population

Fenistil gel should be used on children below 2 years of age only after doctor's advice. Do not use on premature or newborn infants below 4 weeks of age.
In small children and infants, do not use on extensive areas of the skin, particularly on open wounds or inflamed skin (see 4.4 Special warnings and precautions for use)

Method of administration

For dermatological use on intact skin without injuries.

Apply small quantity on the affected area. Then, gently massage with your hand to facilitate penetration of the medicine into the skin. Do not cover with bandages that do not allow air to pass through and do not apply on extensive areas of the skin.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

In case of very severe urticaria events or extensive skin lesions, doctor's or pharmacist's advice should be asked for the topical application of Fenistil to be supplemented by a systemic therapy with an oral form of antihistamine

Prolonged exposure of the treated areas to sun should be avoided.
Use only on intact skin.
Avoid use on large areas of skin, or if there is inflammation or an open wound, especially in babies and small children and in pregnant women or breastfeeding mothers (see Section "4.6 Fertility, Pregnancy and lactation"). In case of extensive damage, the clinical condition of the patient should first be assessed.Avoid contact with eyes, mouth, ears or other mucosal.

Information about excipients

Fenistil gel contains:

- propylene glycol, which may cause locally mild skin irritation. This product contains propylene glycol, therefore do not use it on open wounds or large injured areas or areas with skin damage (such as burns) without asking advice from your doctor or pharmacist.
- benzalkonium chloride, which is a skin irritant, and may cause skin reactions. Do not apply on the breast if you are breastfeeding, because the baby may receive it with the milk. Use during pregnancy and breast-feeding is not expected to be associated with harmful effects on the mother, as the dermal absorption of benzalkonium chloride is minimal. Do not apply on the mucosa.

4.5 Interaction with other medicinal products and other forms of interaction

Interaction studies have not been carried out. The sedative effect of oral dimetindene maleate is increased by concomitant administration of alcohol, procarbazine or other CNS depressants. However, systemic absorption of dimetindene maleate from topical application is very low (about 10% of the dose applied), so such interactions are very unlikely.

Although no interactions are expected, concomitant use with other dermatological drugs is not recommended.

4.6 Fertility, pregnancy and lactation

Pregnancy

Animal studies with dimetindene maleate showed no teratogenic or other direct or indirect adverse effects with respect to pregnancy, foetal development, labour or postnatal development (see section 5.3).

Fenistil gel contains benzalkonium chloride. Use during pregnancy is not expected to be associated with harmful effects on the mother, as the dermal absorption of benzalkonium chloride is minimal. Do not apply to the mucosa.

Fenistil gel should be used in pregnant women only if the benefit of the treatment to the mother outweighs the potential risk to the foetus and only under direction of a physician.

During pregnancy, do not use this product on large skin areas, especially if there is inflammation or an open wound.

Breastfeeding

During breast-feeding do not use on extensive areas of skin, especially if raw or inflamed. Moreover, the product should not be applied to the nipples during breastfeeding. Fenistil gel contains benzalkonium chloride. Therefore, do not apply on the breast if you are breastfeeding, because the baby may receive it with the milk. Use during breast-feeding is not expected to be associated with harmful effects on the mother, as the dermal absorption of benzalkonium chloride is minimal.

Fertility

Animal studies do not indicate toxicity in fertility (see section 5.3). No studies in human are available.

4.7 Effects on ability to drive and use machines

Local forms of Fenistil have no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

The most frequently reported adverse reactions occurring during the treatment were mild and transient skin reactions on the site of application.

Tabulated list of adverse reactions

Undesirable effects are described below per system organ class and frequency. Frequencies are defined as: Very common (≥1/10), Common (≥1/100 to <1/10), uncommon (≥1/1.000 to <1/100), rare (≥1/10.000 to <1/1.000), very rare (<1/10.000), or not known (can not be estimated from available data). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

System Organ	Frequency	Adverse Reaction
Skin and Subcutaneous Tissue Disorders	Not known	Dry skin Skin burning sensation

System Organ	Frequency	Adverse Reaction
	Not known	Allergic dermatitis

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorization 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 ADR Reporting Website: http://www.medicinesauthority.gov.mt/adrportal

4.9 Overdose

Symptoms

In case of accidental oral administration of Fenistil gel, topical form of dimetindene maleate, symptoms similar to the ones from H_1 antihistamine overdose may appear: CNS depression with drowsiness (especially in adults), CNS stimulation and antimuscarinic effects (especially in children and the elderly), including irritability, ataxia, hallucinations, tonic-clonic seizures, mydriasis, dry mouth, flushing, urinary retention and fever. Hypotension may also occur.

Treatment

There is no specific antidote for antihistamine overdose. Treatment should be as clinically indicated or as recommended by the poison centre. The usual first aid must be given, which – in case of oral administration – includes: activated charcoal, saline laxative and conventional cardiopulmonary supportive measures if necessary. No stimulants should be used.

Vasoconstrictors may be used to treat hypotension.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Topical antihistamines for dermatological use
ATCcode: D04AA13.

Mechanism of action

Dimethindene maleate is an H_1 histamine receptor blocker. It presents a high binding affinity for these receptors. It considerably reduces the hyperpermeability of the capillaries which is associated with immediate hypersensivity reactions. In low concentrations induces histamine methyltransferase causing histamine to be

inactivated. When topically applied, dimethindene maleate also presents local anaesthetic properties.

Pharmacodynamic effects

Fenistil Gel is effective in the treatment of itching from various causes and quickly relieve itching and irritation. The base of the gel facilitates the permeability of the active ingredient into the skin. Fenistil gel quickly penetrates the skin and exerts antihistaminic action within a few minutes. The maximum effect occurs within 1 to 4 hours.

5.2 Pharmacokinetic properties

Fenistil gel quickly penetrates the skin and exerts antihistaminic action within few minutes. The maximum effect occurs within 1 to 4 hours.

After topical application in healthy volunteers, the systemic bioavailability of dimethindene maleate is less than 10 % of the dose applied.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity and genotoxicity. There have been no teratogenic effects in rats and rabbits. When administered in rats, dimetindene had no effect on fertility during pre- and post-natal development of the foetus, at doses up to 250times greater than those given to humans.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium Chloride solution 50%,

Disodium Edetate,

Carbomer,

Sodium Hydroxide 30%,

Propylene Glycol,

Purified Water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Do not store above 25° C.

6.5 Nature and contents of container

30 g and 50 g tubes

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Haleon Hellas Single Member Societe Anonyme, under the distinctive title of Haleon Hellas

11 Kifisias Avenue, 151 23 Marousi, Attica, Greece

Tel.: +30 210 2217200

8 MARKETING AUTHORISATION NUMBER

MA1177/00201

9 Date of first AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first Authorisation: 19th April 2007

Date of Renewal: 8th October 2012

10 DATE OF REVISION OF THE TEXT

14th August 2024