Fenistil Gel

Composition

Active substance: Dimethindene maleate.

Excipients: Purified Water, Propylene Glycol, Sodium Hydroxide Solution 30% w/w, Carbomer (Carbopol 974 P), Disodium edetate, Benzalkonium Chloride.

Pharmaceutical form and quantity of the active substance per unit

Dimethindene Maleate 0.1% w/w.

The gel is Colourless to slightly yellowish and practically odourless.

Indications/Possible uses

Urticaria, pruritus, dermatoses, burns, insect bites, allergic dermatitis and eczema.

Posology/Method of administration

Adults and children

Apply 2 to 4 times per day on the areas to be treated in a thin layer and massage lightly.

Contraindications

The product should not be used in case of hypersensitivity to dimethindene maleate or to one of the excipients. The product cannot be used as a treatment for known allergies to insect bites (systemic pharmaceutical forms are available for this purpose).

The product should not be used on open or inflamed wounds, seeping dermatitis or mucosa, or close to the eyes, particularly in children and infants

Warnings and precautions

Propylene glycol: can cause local skin irritations.

Benzalkonium chloride: irritant and can cause skin reactions.

Avoid applying over large areas, especially in infants and young children. Avoid prolonged exposure to the sun of the areas treated.

Interactions

No study of interactions has been conducted.

Pregnancy/Lactation

Pregnancy

Experimental studies conducted with dimethindene on animals revealed no potential teratogenic potential or direct or indirect toxicity with an impact on pregnancy, embryonic development, the development of the fetus, and/or postnatal development (see "Preclinical data").

No clinical data is available concerning use in pregnant women. Therefore, caution is recommended during pregnancy and Fenistil Gel should not be applied to large, burned or inflamed areas of the skin.

Lactation

The precautions are the same as those for pregnancy.

In addition, the gel should not be applied to the nipples when breast-feeding.

Effects on the ability to drive and use machines

Fenistil has no influence or a negligible influence on the ability to drive and use machines.

Undesirable effects

The most commonly reported adverse effects are transient and mild skin reactions in the area of administration.

Adverse effects are listed based on organ class and frequency and are listed below. The frequencies are indicated as follows: 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).

Skin disorders

Uncommon: Skin dryness, burning sensation.

Post-marketing experience

Skin disorders: Very rare cases of allergic dermatitis have been observed.

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.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

https://forms.gov.il/globaldata/getsequence/getsequence.aspx?form

Type=AdversEffectMedic@moh.gov.il

Additionally, you should also report to GSK Israel (il.safety@gsk.com)

Overdose

Symptoms of intoxication resembling those observed in case of overdose with H_1 antihistamines may appear in case of involuntary oral absorption of a large quantity of topical dimethindene maleate. The symptoms are the following: depression of the CNS

with dizziness (especially in adults), stimulation of the CNS and an antimuscarinic effect (especially in children) with excitation, ataxia, hallucinations, tonic-clonic seizures, mydriasis, dry mouth, facial redness, urine retention and fever. Hypotension can also occur.

No specific antidote is known. The usual emergency measures should be begun, including the administration of activated charcoal and osmotic laxatives, as well as stabilisation of the cardiorespiratory system. Do not use a stimulant; vasopressors may be used to normalise hypotension.

Properties/Effects

ATC Code: D04AA13

Dimethindene is an H1 histamine receptor antagonist. It has a strong affinity for H_1-receptors and reduces capillary hyperpermeability that is associated with an immediate hypersensitivity reaction. In case of topical application, dimethindene maleate has a local anaesthetic effect.

Fenistil Gel is effective against pruritus of various origins and quickly soothes itching and irritation. The gel base facilitates penetration of the active substance through the skin.

Pharmacokinetics

Fenistil Gel rapidly penetrates the skin and its antihistaminic effect occurs within a few minutes.

Maximum efficacy is reached after 1 to 4 hours.

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

Preclinical data

Preclinical safety pharmacology repeat-dose toxicity and genotoxicity studies conducted with dimethindene did not indicate a special risk for use in humans. No teratogenic effect was discovered in rats and rabbits. No effect on fertility or peri- and postnatal development of progeny was observed in rats after oral administration of 15 mg/kg and 25 mg/kg.

Shelf life

The expiry date of the product is indicated on the label and packaging.

Specific remarks

Keep medicinal products out of the reach of children.

Do not store above 25°C.

The medicinal product should not be used after the date following “EXP” on the container.

License number

133-24-24020

Presentation

30 g Fenistil gel packed in an aluminum tube sealed with a polypropylene cap.

100 g Fenistil gel packed in an aluminum tube sealed with a polypropylene cap.

Not all pack sizes may be marketed.

Manufacturer

NOVARTIS CONSUMER HEALTH SA, SWITZERLAND

NYON, SWITZERLAND

License Holder and Importer

GSK Consumer Healthcare Israel Ltd., POB 3256, 25 Basel St., Petach Tikva

Approved by MoH on 30.5.2018 (M.C. 2.7.2018)

קוד עלון: FenGel DR v2