Fenistil Gel

Composition

Active substance: Dimethindene maleate.

Excipients: Purified Water, Propylene Glycol, Sodium Hydroxide Solution 30% w/w, Carbomer, Disodium edetate, Benzalkonium Chloride solution 50%.

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.

Maximum duration of use: if no improvement is visible after 7 days, medical advice should be sought.

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).

Warnings and precautions

Avoid applying over large areas of skin, especially in case of open wounds, injuries or damage affecting large areas of skin. This applies in particular in infants and small children.

Avoid prolonged exposure to the sun of the areas treated.

Fenistil Gel contains:

Propylene glycol (E1520 150mg/g): can cause local skin irritations.
Benzalkonium chloride(0.05mg/g): benzalkonium chloride may irritate the skin. You should not apply this medicine to the breasts if you are breast-feeding because the baby may take it in with your milk. As there is only minimal absorption of benzalkonium chloride via the skin, no harmful effects on the mother are expected during pregnancy and breastfeeding.

Do not use on mucous membranes.

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 Gel 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 and subcutaneous tissue disorders

Uncommon: Skin dryness, burning sensation.

Undesirable effects from the post-marketing phase

Skin and subcutaneous tissue disorders:

Very rare cases of allergic dermatitis have been observed.

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. Any suspected adverse event should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il/

Overdose

Symptoms

Accidental ingestion of large quantities of topical dimethindene maleate can result in symptoms of intoxication resembling those observed in case of overdose with H_1

antihistamines. The symptoms are the following: CNS sedation accompanied with drowsiness (especially in adults), stimulation of the CNS and an antimuscarinic effect (especially in children and elderly patients) with excitation, ataxia, hallucinations, tonic-clonic seizures, mydriasis, dry mouth, facial redness, urine retention and fever. Hypotension can also occur.

Measures in the event of overdose

Treatment should take place according to the clinical symptoms or the recommendations of Poisoning center.

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

Pharmacodynamics
No further information.

Clinical efficacy
No further information

Pharmacokinetics
Absorption

Fenistil Gel rapidly penetrates the skin and its antihistaminic effect occurs within a few minutes.
Maximum efficacy is reached after 1 to 4 hours.

Distribution

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

Metabolism
No further information.

Elimination
No further information.

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. In rats no effect on fertility or peri- and postnatal development of offspring were observed after oral administration of 15 mg/kg and 25 mg/kg.

Other information

Shelf life

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

Specific precautions for storage

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

GSK Consumer Healthcare SARL
Route de l'Etraz 1260 Nyon, Switzerland

License Holder and Importer

GSK Consumer Healthcare, Israel Ltd.
P.O.B 3256, Petach Tikva, 4900202

Revised in March 2023 according to MOHs guidelines.

קוד עלון: *FenGel DR v2.1*