APPROVED
The Order of Ministry of Health of Ukraine
06.06.2024 № 979
Registration certificate
№ UA/20481/01/01

INSTRUCTION
for medical use

FAZEX®

Composition:
active substance: dimethindene maleate;
1 g of gel contains 1 mg of dimetindene maleate;
excipients: carbomer 974P, disodium edetate, benzalkonium chloride solution 50 %, propylene glycol, sodium hydroxide pellets, purified water.

Pharmaceutical form. Gel.
Basic physical and chemical properties: homogeneous gel from colourless to slightly yellowish colour, transparent or slightly opalescent.

Pharmacotherapeutic group. Antihistamines for topical use.
ATC code D04A A13.

Pharmacological properties.
Pharmacodynamics.
Dimethindene maleate is a derivative of phenindene and is a histamine antagonist at the level of H_1 receptors. It has an anti-allergic and anti-pruritic effect. Due to the active substance – dimetindene maleate, which is part of the drug Fazex®, when the drug is applied to the skin, itching and irritation accompanying skin allergic reactions are reduced. The drug also has topical anaesthetic properties and cools the skin.
Pharmacokinetics.
When applying the gel topically, thanks to its specially developed base, the active substance quickly penetrates the skin and begins to act within a few minutes. The maximum effect is achieved after 1–4 hours. The systemic bioavailability of the active substance is less than 10% of the dose applied.

Clinical characteristics.
Indications.
Itchy skin, such as insect bites, non-extensive solar erythema, uncomplicated small skin burns and allergic irritation of small areas of skin.

Contraindications.
Hypersensitivity to any component of the drug.

Interaction with other medicinal products and other forms of interaction.
Drug interaction studies were not conducted. Since the systemic absorption of dimetindene maleate with external application of the gel is extremely low, interaction of the drug with other medicinal products is unlikely.
Concomitant use with other drugs for external use is not recommended.

Special warnings and precautions for use.
The drug Fazex® cannot be used in the presence of a known allergy to insect bites. In this case, systemic drugs should be used. It is necessary to avoid the use of the gel in the case of damage to large areas of the skin, especially in children or adolescents. During treatment with the drug, long-term exposure to the sun on the affected skin areas should be avoided.
Excipients.
The drug contains benzalkonium chloride and propylene glycol, which can cause skin irritation.

Use during pregnancy or breastfeeding.
There are no clinical data on the use of the drug in pregnant women. The study of the gel with dimetindene maleate on animals did not cause harmful effects (both direct and indirect) on the course of pregnancy, foetal development, as well as on the further development of the offspring.
However, it is not recommended to use Fazex® gel during pregnancy, unless the benefits outweigh the potential risk to the foetus. In this case, the drug can only be used as prescribed by a doctor.
It is not recommended to apply Fazex® gel on large areas of skin, especially on damaged or inflamed skin. The same applies to breastfeeding women. In addition, breastfeeding women should not apply the gel to the nipples of the mammary glands.

Ability to affect the speed of reaction to drive or use other mechanisms.
Dimethindene maleate when used externally does not affect or has a negligible effect on the speed of reaction when driving a motor vehicle or working with other mechanisms.

Administration and dosage.
Administration details.
Fazex® gel is intended for external use on skin that does not have damage to its integrity. Apply a small amount of gel to the affected skin, gently rubbing. The area of skin treated with the gel should not be covered with an airtight bandage. Also, the drug should not be applied to large areas of the skin.
If there is no improvement after 7 days of using the drug, a doctor should be consulted. In case of very severe itching or damage to an extensive area, in addition to topical treatment, systemic therapy with oral antihistamines should be used after consulting a doctor.
Dosage.
Adults and children over 2 years old.
Apply the gel 2–4 times a day.
Children under 2 years of age.
The drug can be used only as prescribed by a doctor.

Children.
For children under 2 years of age, the drug can be used only as prescribed by a doctor. The drug should not be used in premature babies within 4 weeks after birth. Babies and young children should not apply the gel to large areas of skin, especially damaged or inflamed skin (see the section “Special warnings and precautions for use”).

Overdose.
To date, there have been no reports of drug overdose.
In case of accidental swallowing of a large amount of Fazex® gel, the doctor should be consulted immediately.
Some symptoms characteristic of an overdose of H1-antihistamines for systemic use may be observed: central nervous system depression accompanied by drowsiness (mainly in adults),

stimulation of the central nervous system and antimuscarinic effect (especially in children and the elderly), including agitation, ataxia, hallucinations, tonic-clonic convulsions, mydriasis, dry mouth, facial hyperemia, urination disorders, fever, arterial hypotension is also possible.
In case of overdose, it is necessary to take measures recommended by the medical institution in accordance with the symptoms that appear.

Adverse reactions.
The most common adverse effects are minor and short-term reactions on the skin at the site of application of the gel. Since the medicine contains benzalkonium chloride and propylene glycol, symptoms of skin irritation may occur.
Skin and connective tissues disorders.
Frequency unknown (cannot be determined based on available data): dry skin, burning sensation of the skin, allergic reactions (including skin rashes), itching, swelling, allergic dermatitis, urticaria*.
*Data obtained in the process of post-marketing surveillance.

Reporting of suspected adverse reactions.
Reporting of adverse reactions after the registration of a medicinal product is important. This makes it possible to monitor the benefit/risk ratio when using this medicinal product. Medical and pharmaceutical workers, as well as patients or their legal representatives should be notified of all cases of suspected adverse reactions and lack of efficacy of the medicinal product through the Automated Pharmacovigilance Information System at the link: https://aisf.dec.gov.ua

Shelf life.
2 years.

Storage conditions.
Store in the original package at a temperature below 25°C.
Keep out of the reach of children.
After the first opening of the tube, the drug should be stored for no more than 60 days.

Package.
30 g in an aluminium tube. 1 tube in a carton package with instruction for medical use.

Category of supply.
Without prescription.

Manufacturer.
KUSUM HEALTHCARE PVT LTD.

Location of manufacturer and its address of its business activity.
SP-289 (A), RIICO Industrial area, Chopanki, Bhiwadi, Dist. Alwar (Rajasthan), India.

Date of last revision.