

Regulatory Affairs

Fenistil 1 mg/ml Oral Drops

Dimethindene maleate

Summary of Product Characteristics

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1. NAME OF THE MEDICINAL PRODUCT

Fenistil NEW

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of Fenistil NEW contains 1 mg of dimethindene maleate.

For excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Oral Drops 0,1%

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Symptomatic treatment of allergic diseases: urticaria, allergic diseases of the upper respiratory tract, such as hay fever and perennial allergic rhinitis, food and drug allergies.

Itching of various origins, with the exception of itching with cholestasis. Itching in diseases accompanied by a rash, such as chicken pox. Itching after insect bites.

As an aid in eczema and other itchy dermatoses of an allergic origin.

4.2. Posology and method of administration

Adults:

The recommended daily dose is 3 to 6 mg dimethindene maleate divided in three intakes, i.e 20 to 40 drops three times a day.

In patients who have a tendency to drowsiness, the recommended dosage is 40 drops before sleeping, and 20 drops in the morning, during breakfast.

Maximum duration of use is 14 days without consulting a doctor.

Children:

Children to 1 year

Children from 1 month to 1 year of age can use Fenistil NEW drops only after consulting a doctor and solely for medical reasons established for antihistamines. Exceeding the recommended dose is not allowed.

Caution is recommended in case of administration in infants aged less than 1 year: the sedative effect may be associated with episodes of sleep apnoea.

The usual daily dose is 0.1 mg/kg body weight, i.e 2 drops/kg body weight daily.

Daily dose should be divided in three intakes.

Children from 1 month to 12 year of age usual daily dose is based on body weight (kg) and according to below table;

Age/Body weight (kg)	Dosage in mg	Dosage in drops
1 month - 1 year/ 4,5-15 kg	0,15-0,5 mg 3 times daily	3-10 drops 3 times daily
1-3 years/ 15-22,5 kg	0,5-0,75 mg 3 times daily	10-15 drops 3 times daily
3-12 years/ 22,5-30 kg	0,75-1 mg 3 times daily	15-20 drops 3 times daily

20 drops = 1 ml = 1 mg dimethindene maleate.

1 drops = 0,05 mg dimethindene maleate.

Children above 12 years of age
Dosage is the same as for adults.

Method of administration

For oral administration.

When used in children, Fenistil NEW drops should be added to a bottle with warm baby food just before feeding, as drops should not be exposed to high temperature. If the baby is already fed from a spoon, drops can be given undiluted. Drops taste good.

4.3. Contraindications

Hypersensitivity to dimethindene maleate or to any of the excipients (see 6.1. list of excipients).

Infants less than one month of age, particularly premature infants.

4.4. Special warnings and special precautions for use

Caution is recommended in case of administration in patients with glaucoma, urinary retention on the background of prostatic hyperplasia, chronic obstructive pulmonary diseases.

H1 and H2 histamine receptor blockers should be used with caution in patients with epilepsy. In young children, the use of antihistamines can lead to agitation.

Administration in infants from 1 month to 1 year of age:

Caution is recommended in case of administration in infants aged less than 1 year: the sedative effect may be associated with episodes of sleep apnoea.

Fenistil NEW should be administered in infants one month to one year of age only on medical advice and for a strict medical indication. Recommended dose should not be exceeded.

Caution is recommended in elderly patients, as this age group is more susceptible to adverse reactions such as agitation and fatigue. Use in confused elderly patients should be avoided. Do not exceed the recommended dose and duration without consulting a doctor.

The drug contains propylene glycol (100 mg in 1 ml), benzoic acid (1 mg in 1 ml), less than 1 mmol sodium (23 mg in 1 ml), i.e. practically does not contain sodium.

Propylene glycol in the medicine can have the same effects as drinking alcohol and increase the likelihood of side effects.

4.5. Interactions with other medicinal products and other forms of interaction

The simultaneous use of drugs that have a depressing effect on the central nervous system can cause an increase in their action and entail the occurrence of undesirable and life-threatening consequences. Such medicines include opioid analgesics, anticonvulsants, antidepressants (tricyclic antidepressants and monoamine oxidase inhibitors), other antihistamines and antiemetics, antipsychotics, anxiolytics, sleeping pills, scopolamine and alcohol.

Tricyclic antidepressants and anticholinergics (e.g., bronchodilators, gastrointestinal antispasmodics, mydriatics, urological antimuscarins) in combination with antihistamines can have an additional antimuscarinic effect, as well as increase the risk of glaucoma exacerbation or urinary retention.

Caution should be exercised with the simultaneous use of antihistamines and procarbazine in order to reduce the risk of possible potentiation and to minimize the CNS depression syndrome.

4.6. Pregnancy and lactation

Pregnancy

Animal studies with dimethindene have shown neither teratogenic potential, nor direct or indirect effect of dimethindene in the course of pregnancy, nor other adverse effects on the development of embryo and/or the foetus or postnatal development.

Clinical studies involving pregnant women have not been conducted.

Should be taken during pregnancy only in high necessity cases.

Lactation

It can be assumed that dimethindene may pass into breast milk. It is not

recommended to use the drug during breastfeeding.

Fertility

No fertility data available.

4.7. Effects on ability to drive and use machines

The use of the drug Fenistil NEW may reduce the ability to react quickly. During the period of use of the drug, caution should be exercised for patients whose activities require an increased concentration of attention and quick reactions (work with mechanisms).

4.8. Undesirable effects

Side effects include somnolence, which is especially evident at the beginning of treatment. In very rare cases allergic reactions can occur.

The adverse reactions are listed below according to system class and frequency. The frequencies are defined as follows: Very common ($\geq 1/10$), common ($< 1/10, \geq 1/100$), uncommon ($< 1/100, \geq 1/1,000$), rare ($< 1/1,000, \geq 1/10,000$), very rare ($< 1/10,000$). Within each group, adverse reactions are presented in decreasing order of severity.

Immune system disorders

Very rare: manifestations of anaphylactoid reactions, including facial swelling, laryngeal edema, rash, muscle spasms and shortness of breath.

Psyche disorders

Rare: agitation.

Nervous system disorders:

Very common: fatigue (11,8%).

Common: Somnolence, nervousness.

Rare: headache, dizziness.

Gastrointestinal disorders:

Rare: gastrointestinal disorders, nausea, dry mouth and throat.

Reporting Adverse Reactions:

It is important to report suspected adverse reactions after drug registration in order to ensure continuous monitoring of the benefit-risk ratio of the drug. Health workers are advised to report any suspected adverse reactions through national reporting systems for adverse reactions and drug inefficiencies.

If the patient has any adverse reactions, he is advised to consult a doctor. This recommendation applies to any possible adverse reactions, including those not listed in the package leaflet. You can also report adverse reactions to the information database on adverse reactions (actions) of drugs, including reports of drug inefficiencies. By reporting adverse reactions, you help to get more information about the safety of the drug.

4.9. Overdose

Symptoms and signs of overdose with H₁-antihistamines may include: CNS depression with drowsiness (mainly in adults), CNS stimulation and antimuscarinic effects (especially in children), including agitation, ataxia, tachycardia, hallucinations, tonic-colonic convulsions, mydriasis, dry mouth, "flushing" of blood to the face, urinary retention and fever; low blood pressure, coma, collapse.

There is no specific antidote for overdose with antihistamines. The usual emergency assistance must be undertaken, including activated charcoal, saline laxative and usual cardiorespiratory supportive measures. Stimulants should not be used, vasopressors may be used to treat hypotension.

In case of overdose, generally accepted medical measures should be taken in accordance with the clinical symptoms.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group

Antihistamine (histamine H₁-receptor antagonist). ATC code: R06AB03.

Dimetindene - a blocker of H₁-histamine receptors, is a competitive histamine antagonist. In low concentrations, it stimulates histamine methyltransferase, which leads to histamine deactivation. Dimethindene has a strong affinity for H₁ receptors and is a powerful mast cell stabilizer. In addition, it has a local anesthetic effect. Dimetinden has no effect on H₂ receptors. Dimethindene also acts as an antagonist of bradykinin, serotonin and acetylcholine. It is a racemic mixture in which R - (-) - dimethindene has a higher H₁ antihistamine effect.

This leads to a decrease in the increased permeability of capillaries, which is observed with allergic reactions of an immediate type.

In combination with H₂ antihistamines, dimetindene suppresses almost all the effects of histamine in the bloodstream.

5.2. Pharmacokinetic properties

Absorption

The systemic bioavailability of dimethindene from drops is approximately 70%. The beginning of action can be expected in 30 minutes and the main effect within 5 hours. Peak serum concentrations of dimethindene are reached within two hours.

Distribution

At concentrations from 0.09 µg / ml to 2 µg / ml, the connection of dimetindene with plasma proteins is approximately 90%. *Metabolism*

Metabolic reactions include hydroxylation and methoxylation of the compound in hepar.

Breeding

The half-life of serum is approximately 6 hours. It is excreted along with metabolites with bile and urine. 5-10% of the administered dose is excreted unchanged in the urine.

5.3. Preclinical safety data

Preclinical data on the active substance reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity and genotoxicity. No teratogenic effects were detected in rats and rabbits. Dimethindene in rats did not influence fertility nor the peri-and postnatal development of the offspring at doses 250 times higher than the human dose.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Disodium phosphate dodecahydrate;

Citric acid monohydrate;

Benzoic acid;

Disodium edetate;

Saccharin sodium;

Propylene glycol;

Purified water.

6.3. Shelf life

24 months.

6.4. Special precautions for storages

Store below 25°C, keep the bottle in the outer carton. Keep out of the reach of children. After opening keep the bottle not more than 24 months.

6.5. Nature and contents of container

20 ml in a dark glass bottle, equipped with a dropper dispenser made of low-density polyethylene and a polypropylene cap with a child-resistant function and a first opening control system.

1 bottle with instructions for use is enclosed in a cardboard box.

7. MARKETING AUTHORISATION HOLDER

GSK Consumer Healthcare SARL, Switzerland.

(Route de l'Etraz, Case postale 269, 1260 Nyon, Switzerland).

8. HOLDER OF REGISTRATION CERTIFICATE

GSK Consumer Healthcare SARL, Switzerland

(Route de l'Etraz, Case postale 269, 1260 Nyon, Switzerland).

9. DATE OF REVISION OF THE TEXT: 23.05.2022