Fenistil®

Long-acting capsules
Antihistaminic, antipruritic, antiallergic

Composition

Active ingredient: Dimetindeni maleas 4 mg, Acidum glutamicum, Excip. pro caps.

Properties/Effects

Dimethindene maleate, a phenindene derivative, is an H_1-receptor antagonist.
Dimethindene maleate also exerts antikinin activity and slight anticholinergic and sedative effects, but has no antiemetic action.
Accordingly, it reduces the capillary hyperpermeability associated with immediate-type hypersensitivity reactions.
When combined with an H_2 antihistamine, it suppresses most of the circulatory effects of histamine.
The reactions caused by pollen are diminished if dimethindene is taken prophylactically.
A study investigating the inhibition of papules and cutaneous erythema induced by histamine showed that the effect of a single dose of Fenistil capsules 4 mg lasted for at least 24 hours.
Alertness and performance tests have not revealed any significant differences from placebo when Fenistil capsules 4 mg was taken at the recommended dosage. There is a light sedative effect if taken in the morning and none if taken in the evening.

Pharmacokinetics

Peak serum dimethindene levels were reached approximately 7 to 12 hours after a single dose of Fenistil capsules 4 mg. The apparent elimination half-life in the serum was about 11 hours.
Pharmacokinetic results plotted a linear course after the repeated administration of Fenistil capsules 4 mg taken once daily, and no accumulation was observed.
At concentrations between 0.09 and 2 µg/ml, binding of dimethindene to human plasma proteins is approximately 90%. Metabolic reactions include hydroxylation and methoxylation of the compound. Dimethindene and its metabolites are eliminated in the bile and urine.
The volume of distribution (V_D) is 293 liters. The total clearance (Cl_{tot}) is 311 ml/min or 19 l/h. The fraction not eliminated in the urine (Q_0) is 90 % or 0.90.

Indications/Therapeutic use

Symptomatic treatment of allergic disorders: skin: urticaria, pruritus associated with eruptive dermatoses (eczema and related conditions); respiratory tract: seasonal rhinitis (hay fever) and perennial rhinitis.

Dosage/Directions for use

Adults and children over 12 years of age
The daily dosage is 1 capsule per day, to be taken in the evening. The capsule should be swallowed whole, without chewing.
Patients working at night should take Fenistil capsules 4 mg before going to bed.
This galenic form is not suitable for the treatment of children less than 12 years of age, for whom Fenistil drops are recommended.
The duration of treatment should not be longer than 25 days.

Restrictions on use

Contraindications
Hypersensitivity to one of the components.
Precautions
Observe the usual precautions if the patient suffers from glaucoma, urinary retention associated with urethro-prostatic disorders or chronic asthma.
Objective performance tests have shown that Fenistil capsules 4 mg, taken at the recommended dosage, does not generally impair concentration. Certain patients may, however, occasionally become tired or less alert, in particular if the product is taken in the morning. Caution is indicated, therefore, in patients who need to drive or perform tasks requiring concentration (for example, operate machinery).
This galenic form is not suitable for the treatment of children less than 12 years of age, for whom Fenistil drops are recommended.
Pregnancy, breast feeding
Animal reproduction studies have not demonstrated any risk to the fetus, but no controlled trials have been performed with pregnant women. Fenistil capsules 4 mg should only be used during pregnancy if the treatment is essential and the expected benefits outweigh the potential risks.
One animal study has shown that very small quantities of dimethindene and/or its metabolites pass into the mother's breast milk. The use of Fenistil capsules 4 mg is not recommended during breast feeding.

Undesirable side effects

In controlled clinical trials with Fenistil capsules 4 mg, cases of tiredness or transient drowsiness were occasionally reported, although their incidence was similar to that observed with placebo.
Occasionally, headache, excitement, nausea and other gastrointestinal symptoms, dryness of the mouth and vertigo have also been observed.
Rare cases of edema, skin rash, muscular spasm and respiratory impairment have been reported during the post-marketing surveillance of other presentations of Fenistil.

Interactions

The sedative effect of central nervous system depressants such as tranquillizers, hypnotics and alcohol may be enhanced. The simultaneous administration of MAO inhibitors may increase the anticholinergic and CNS depressant effects of antihistamines; concurrent use is not, therefore, recommended.
Tricyclic antidepressants and anticholinergic agents may produce an additive anticholinergic effect with antihistamines, with possible exacerbation of glaucoma or urinary retention.

Overdosage

As with other H_1 antihistamines, overdosage can produce the following symptoms: CNS depression with drowsiness (mainly in adults), CNS stimulation and antimuscarinic effects (especially in children) including the following: excitement, ataxia, tachycardia, hallucinations, tonic-clonic spasms, mydriasis, dry mouth, facial flushing, urinary retention and fever. Hypotension may also occur. Terminally, there may be deepening coma with cardiorespiratory collapse and death. No fatal outcome of overdosage has ever been reported with Fenistil capsules 4 mg.
There is no specific antidote for antihistamine overdosage. The standard emergency measures should be taken: forced emesis, gastric lavage if vomiting is ineffective, administration of activated charcoal, saline laxatives, together with the usual cardiorespiratory support. Stimulants should not be administered, but vasopressor agents may be used for treating hypotension.

Further remarks

Storage
Protect from light, moisture and heat. The medicine may be used only up to the date ‹EXP› shown on the package.

Packaging

Pack of 10 capsules.

Novartis Consumer Health SA
Nyon Switzerland

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