FENISTIL® DROPS

Composition
Active substance: Dimethindene maleate.
Excipients:
Purified Water, Propylene Glycol, Disodium Phosphate dodecahydrate, Citric Acid Monohydrate, Benzoic acid, Disodium edetate, Saccharin sodium

1 ml Fenistil drops contains 2.24 mg of sodium

Pharmaceutical form and quantity of the active substance per unit

Oral drops, solution
1 mL (=20 drops) contains: 1 mg of dimethindene maleate.

Indications/Possible uses
Antipruritic, antihistaminic and antiallergic.

Posology/Method of administration
Adults and adolescents over 12 years of age:
The daily recommended dose is 3 to 6 mg of dimethindene maleate divided into 3 doses; this corresponds to:
Drops 1 mg/ml: 20-40 drops, 3x per day.

In patients with a tendency to drowsiness, it is recommended to prescribe 40 drops before bedtime, and 20 drops in the morning at breakfast.

Children:
In small children from 1 month to 1 year of age, Fenistil Drops should only be used according to a doctor's recommendations and upon strict medical indication for antihistamines. The recommended dose should not be exceeded.

Caution should be used when administering drops to children under 1 year of age. The sedative effect may be associated with episodes of sleep apnoea.
The recommended daily dose is 0.1 mg/kg of body weight per day (this corresponds to 2 drops per kg of body weight per day, divided into 3 doses).
The usual daily doses for children from 1 month to 12 years of age and based on body weight, are therefore the following:

Age/Weight	Dose in mg	Dose in drops
1 month to 1 year/ 4.5-15 kg	0.15-0.5 mg three times per day	3-10 drops three times per day
1-3 years/15-22.5 kg	0.5-0.75 mg three times per day	10-15 drops three times per day
3-12 years/22.5-30 kg	0.75-1 mg three times per day	15-20 drops three times per day

20 drops = 1 mL = 1 mg of dimethindene maleate.
1 drop = 0.05 mg of dimethindene maleate.

Fenistil Drops cannot withstand high temperatures; before feeding pour them directly into a warm feeding bottle. If the baby is already eating with a spoon, give the drops in a teaspoon; they have a pleasant taste.

Maximum duration of use: Fenistil drops must not be taken for more than 14 days without approval from a doctor

Contraindications
Hypersensitivity to the active substance or to one of the excipients in the composition.
Neonates under 1 month old, in particular premature babies.

Warnings and precautions
Follow the usual precautions in case of glaucoma, urinary retention, for example associated with prostatic hypertrophy, chronic obstructive pulmonary disease.

Like all H1 and H2 receptor agonists, caution should be used in patients with epilepsy. Antihistamines may cause excitation in young children.

Use in young children from *1 month to 1 year of age*

Caution should be used when administering drops to children under 1 year of age: the sedative effect may be associated with episodes of sleep apnoea.

In small children from *1 month to 1 year of age, Fenistil Drops should only be administered after a medical consultation and upon strict medical indication for antihistamines. The recommended dose should not be exceeded.*

Use with caution in elderly patients, as this age group is more susceptible to undesirable effects such as agitation and fatigue. Use in confused elderly patients should be avoided. The recommended dose and duration of use must not be exceeded without a doctor's approval.

This medicine contains propylene glycol 100 mg/ml (or per 20 drops).

This medicine contains benzoic acid 1 mg/ml (or per 20 drops).
This medicine contains less than 1 mmol (=23 mg) of sodium per 1 ml (or per 20 drops), that is to say, they are essentially "sodium-free"***.***

Interactions
It is expected that the concomitant use of two or more medicinal products with a sedative effect on the central nervous system leads to increased depression of the CNS. This may have undesirable, even fatal consequences. These medicinal products are, in particular, analgesics (opioids), anticonvulsants, antidepressants (tricyclic antidepressants and MAO inhibitors), antihistamines, anti emetics, antipsychotics, anxiolytics, hypnotics, scopolamine and alcohol.

Tricyclic antidepressants and anticholinergics (for example, bronchodilators, gastrointestinal spasmolytics, mydriatics, urological antimuscarinics) may cause an

additional antimuscarinic effect with antihistamines, and increase the risk of exacerbation of glaucoma or urinary retention.

In order to reduce the risks of CNS depression or possible potentiation, caution must be exercised when administering procarbazine and antihistamines concomitantly.

Pregnancy/Lactation

Pregnancy

In animal studies with dimethindene maleate, no teratogenic potential and no direct or indirect toxicity with an impact on pregnancy, embryonic development, the development of the fetus, and/or postnatal development was revealed.

There are no available clinical data concerning use in pregnant women. During pregnancy, *Fenistil Drops* should only be used under a strict indication.

Lactation

It is likely that dimethindene maleate is excreted in human milk. Taking *Fenistil Drops* is not recommended while breastfeeding.

Effect on the ability* to *drive and use machines

Use of *Fenistil Drops* can affect reactions. Caution should be used when driving a vehicle or performing tasks requiring vigilance (for example, using machines).

Undesirable effects

Undesirable effects include drowsiness occurring in particular at the start of treatment. Allergic reactions occur very rarely.

Adverse effects are listed by system organ class and by frequency. The frequencies are defined 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). In each frequency group, the undesirable effects are indicated in order of decreasing severity.

Immune system disorders

Very rare: anaphylactic reaction, including facial oedema, pharyngeal oedema, skin rash, muscle spasms, and dyspnoea.

Psychiatric disorders

Rare: agitation.

Nervous system disorders

Very common: fatigue (11.8%).
Common: drowsiness, nervousness.
Rare: headaches, dizziness.

Gastrointestinal disorders

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

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://sideeffects.health.gov.il/

Overdose

Symptoms

The signs and symptoms of overdose by H1 antihistamines include: central nervous system depression accompanied by drowsiness (primarily in adults), central nervous system stimulation, and antimuscarinic effects (in particular in children and elderly patients) including excitation, tachycardia, ataxia, hallucinations, shakiness, tonic or clonic muscle spasms, mydriasis, dry mouth, facial redness, urinary retention and fever. The potential consequences are, hypotension, coma and cardio-respiratory arrests.

Treatment of overdose

Treatment must be consistent with the clinical symptoms or Tox Info Suisse guidelines.

Properties/Effects
ATC Code: R06AB03 (H1 histamine receptor agonist)

Mechanism of action

Dimethindene is a competitive inhibitor of the histamine H1 receptors. At a low concentration, it stimulates histamine-methyltransferase, causing deactivation of histamine. It has a strong affinity for H1 receptors and is a powerful mastocyte stabilizer. It also has a local anaesthetic effect. It has no effect on H2 receptors. Dimethindene also has an agonistic effect on bradykinin, serotonin, and acetylcholine. It is a racemic mixture in which R-(-)-dimethindene presents the most powerful H1 antihistaminic effect. It leads to decreased capillary hyperpermeability associated with immediate hypersensitivity reactions.
In association with an H2, antihistamine, it suppresses practically all the circulatory effects of histamine.

Pharmacodynamics
No additional information.

Clinical efficacy
No information.

Pharmacokinetics

Absorption

The systemic bioavailability of dimethindene in drops is approximately 70%. The onset of action can be expected after 30 minutes and the main effect is observed within 5 hours. After administration of an oral solution, maximum blood levels were reached within 2 hours.

Distribution

At concentrations between 0.09 µg/mL and 2 µg/mL, approximately 90% of dimethindene is bound to human plasma proteins.

Metabolism

Metabolic reactions include hydroxylation and methoxylation of the compound.

Elimination

The serum elimination half-life is approximately 6 hours. Dimethindene and its metabolites are excreted via the urine and bile. 5 to 10% of the dose administered is excreted unchanged in the urine.

Preclinical data
Classic preclinical pharmacological safety studies, repeat-dose toxicity and genotoxicity studies did not reveal any specific risk for use in humans. No teratogenic effect was observed in rats and rabbits. A dose 250 times greater than that recommended for administration in humans had no effect on fertility or on peri- and post-natal development in rats.

Other information

Shelf life

The expiry date of the product is indicated on the label and packaging.
After initial opening, may be used for 6 months.

Special precautions for storage

Keep out of the reach of children.
Store away from light and at room temperature (15-25°C).

License number
034-23-22255

Presentation
20 mL glass bottle

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

FenDrp DR v1.1

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