Tavegyl®

Antiallergic and antipruritic agent
Antialérgico y antipruriginoso
Antiallergique et antiprurigineux

Composition
Active principle: Clemastinum (clemastine fumarate).
Tablet 1.0 mg (scored);
Ampoule (2 ml) 1.0 mg/ml.
Excipients: Sorbitolum, Ethanolum, Propylenglycolum; Natrii citras; Aqua q.s. ad solut. pro 2 ml (ampoule).

Properties/Effects
Tavegyl is an H_1 histamine receptor antagonist of the piperidine derivative group (pyrrolidine type). It selectively inhibits the H_1 histamine receptors and reduces capillary permeability. Tavegyl possesses antihistaminic and antipruritic properties. Its effect can last for up to 12 hours.

Pharmacokinetics
Following oral administration, Tavegyl (clemastine) is almost completely absorbed through the gastrointestinal mucosa. Peak plasma concentration is attained in 2–5 hours. The antihistaminic effect reaches its peak after 5–7 hours and generally lasts for 10–12 hours, and in some cases for as long as 24 hours.
Clemastine is 95% bound to plasma proteins. Its elimination from the plasma is biphasic, with half-lives of 3.6 ± 0.9 hours and 37 ± 16 hours. Clemastine undergoes extensive biotransformation in the liver. The metabolites are 45–65% excreted via the kidneys, whereas the unchanged substance is barely detectable in the urine. In nursing mothers, the medicine passes into the breast milk in appreciable quantities.

Indications/Method of use
Tablets
Hay fever and other forms of allergic rhinitis.
Urticaria, including dermatographia.
Pruritus, itching dermatoses.
Adjuvant treatment of acute and chronic eczema, contact eczema and iatrogenic eruptions.
Insect stings and bites.
Ampoules
Adjuvant treatment of anaphylactic and anaphylactoid shock and Quincke's oedema (angioneurotic oedema).
Prevention or treatment of allergic and pseudo-allergic reactions, e.g. to contrast media, during blood transfusion or during the histamine test.

Dosage/Directions for use
Tablets
Swallow the Tavegyl tablets with a little water before meals.
Adults and children over 12 years of age: 1 tablet morning and evening. In stubborn cases, up to 6 tablets may be given daily; the maximum single dose is 2 tablets.
Children 6–12 years of age: before breakfast and at bedtime: ½–1 tablet.
Ampoules
Adults: in general, 1 ampoule (2 ml = 2 mg) by i.v. or i.m. injection morning and evening.
Prophylaxis: 1 ampoule (2 ml) by slow i.v. injection just before the anticipated appearance of an anaphylactic or histaminergic reaction. The content of the ampoule may be diluted 1:5 with isotonic saline or 5% glucose solution.
Children: 0.025 mg/kg daily in 2 i.m. injections.

Restrictions on use
Contraindications
Known hypersensitivity to Tavegyl or to other antihistamines of similar structure.
Tavegyl must not be administered to children under 1 year of age.
Precautions
Warning: intra-arterial injection must be avoided absolutely. Intravenous injection must be performed slowly (over 2 to 3 minutes).
Tavegyl may have a sedative effect, particularly when administered parenterally. This must be taken into account when driving vehicles or using machines. The sedation may also be very marked in young children.
Antihistamines should be used with caution in the case of narrow-angle glaucoma, stenosing peptic ulcer, pyloroduodenal obstruction or prostatic hypertrophy with postmictional urinary retention and bladder neck obstruction.
Pregnancy, breast feeding
No teratogenic effect has been found in animal studies, but embryotoxicity was observed in rats given very large doses. There have been no controlled studies in pregnant women. Consequently, this medicine may be administered only if the potential benefit outweighs the risk to the foetus.
If it is absolutely necessary to give Tavegyl to a nursing mother, it is essential to discontinue breast feeding.

Undesirable side effects
Fatigue and sedation, particularly following parenteral administration and in young children. Occasionally CNS stimulation, especially in children. Rarely dry mouth, headaches, dizziness, skin rash, nausea, stomachache and constipation.
Hypersensitivity reactions with respiratory distress and/or states of shock have been observed in a few very rare cases after the i.v. injection of Tavegyl.

Interactions
Antihistamines enhance the effects of sedatives, hypnotics, MAO inhibitors and alcohol.

Overdosage
Symptoms
The effects of antihistamine overdosage on the central nervous system may be expressed by depression or by excitation or by all intermediate states. Excitation is particularly observed in children. Anticholinergic symptoms may also arise, such as dry mouth, dilated pupils with fixed gaze, hot flushes and gastrointestinal upsets.
Treatment
Elimination of the medicine by gastric lavage followed by the administration of activated charcoal and symptomatic treatment.

Further remarks
Like all medicines, Tavegyl should be kept out of the reach of children.
The product may be used up to the date (EXP) shown on the pack. Do not store above 30 °C.

Packaging
Tablets (scored): packs of 20 and 100 tablets.
Ampoules (2 ml): pack of 5 ampoules.
For further pack sizes, see country-specific information.

Manufacturer: see folding box.

Novartis Consumer Health SA Nyon Switzerland

Information updated: October 1994.