SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

TAVEGIL TABLETS

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Clemastine hydrogen fumarate 1.34mg (equivalent to clemastine base 1mg)

Excipients with known effect:

Lactose Monohydrate 107.66mg/Tablet

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

White, uncoated, round, 7 mm in diameter with beveled edges, smooth on one side and marked with “OT” and scored with a single breakline on the other.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Allergic rhinitis, including hay fever and perennial rhinitis, vasomotor rhinitis. Allergic dermatoses, including pruritus, atopic eczema and contact dermatitis. Urticaria. Angioneurotic oedema, drug allergy.

4.2 Posology and method of administration

Adults

1mg clemastine base (one tablet) night and morning.

In individual cases the dose may be increased to 6mg clemastine base daily if

necessary (six tablets).

Children

1 to 3 years: 250 microgrammes to 500 microgrammes clemastine base (¼ - ½ tablet night and morning.

3 to 6 years: 500 microgrammes clemastine base (½ tablet) night and morning.

6 to 12 years: 500 microgrammes to 1000 microgrammes clemastine base (½ - 1 tablet) night and morning.

Use in the elderly

No evidence exists that elderly patients require different dosages or show different side effects from younger patients.

Oral administration only.

Maximum duration of use: Clemastine fumarate should not be used for more than 14 days without consulting a doctor. Do not exceed the recommended dose

4.3 Contraindications

TAVEGIL is contraindicated in patients with a known hypersensitivity to clemastine or other arylalkylamine antihistamines, or any of the excipients.

TAVEGIL should not be given to porphyric patients.

TAVEGIL should not be given to children below one year of age.

4.4 Special warnings and precautions for use

Antihistamines should be used with caution in patients with:

- narrow-angle glaucoma
- stenosing peptic ulcer
- pyloroduodenal obstruction
- prostatic hypertrophy with urinary retention and bladder neck obstruction.
- children due to the risk of excitability in this special population (see section 4.8)
- epilepsy or history of seizures
- in the elderly, who are more likely to experience adverse effects such as paradoxical excitation. Avoid use in elderly patients with confusion.

- Do not exceed recommended dosage and duration of use without consulting a health care provider (See Dosage and Administration).

Excipient Warning
Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose -galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Antihistamines potentiate the sedative effects of Central Nervous System

(CNS) depressants including hypnotics, monoamine-oxidase inhibitors

(MAOI's), antidepressants, anxiolytics, opioid analgesics and alcohol.

Patients should be advised to avoid alcoholic drinks.

As clemastine has some anticholinergic activity, the effects of some anticholinergic drugs (e.g. atropine, tricyclic antidepressants) may be potentiated.

4.6 Fertility, pregnancy and lactation

TAVEGIL should not be given during pregnancy and breast-feeding.

4.7 Effects on ability to drive and use machines

TAVEGYL has moderate influence on the ability to drive and use machines, due to the antihistamine sedative effect of clemastine, however, patients should be warned not to take charge of vehicles or machinery until the effect of TAVEGIL treatment on the individual is known.

4.8 Undesirable effects

Adverse reactions are listed below, by system organ class and frequency. Frequencies
are defined as: very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1,000, <1/100); rare (≥1/10,000, <1/1,000) very rare (<1/10,000). or not known (can not to beestimated from available data). Adverse reactions identified during post-marketing use are reported voluntarily from a population of uncertain size, the frequency of these reactions is not known but likely to be rare or very rare

MedDRA SOC	Adverse Reaction	Frequency
Immune system disorders	Anaphylactic shock	Rare
	Hypersensitivity reactions	Rare
Psychiatric disorders	Excitability, especially in children	Rare
Nervous system disorders	Sedation	Common
	Dizziness	Uncommon
	Headache	Rare
	Fatigue	Common
Cardiac disorder	Tachycardia	Very rare
	Palpitations	Very rare
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Rare
Gastrointestinal disorder	Abdominal pain	Rare
	Nausea	Rare
	Dry mouth	Rare
	Constipation	Very rare
Skin and Subcutaneous tissue disorders	Skin rash	Rare
General system disorders	Asthenia	Rare

Reporting of suspected adverse reactions

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. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Symptoms: the effects of antihistamine overdose may vary from CNS depression to stimulation such as depressed level of consciousness, excitability, hallucinations, or convulsions. Anticholinergic symptoms such as dry mouth, mydriasis or flushing, gastrointestinal reactions and tachycardia may also develop.

Treatment: Treatment consists of symptomatic therapy or as recommended by the national poisons centres, where applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamines: H1-receptor, ATC code R06AA04

Mechanism of action and pharmacodynamic effects

TAVEGIL (clemastine) is an H_1-recptor antagonist. It belongs to the benzhydryl ether group of antihistamines. TAVEGIL inhibits selectively the histamine receptors of the H_1 type and reduces capillary permeability. It exerts a potent antihistaminic and antipruritic effect with a fast onset and long duration of action up to 12 hours.

5.2 Pharmacokinetic properties

Absorption

Following oral administration TAVEGIL (clemastine) is almost completely absorbed from the gastrointestinal tract. Peak plasma concentrations are attained within 2-4 hours. The antihistaminic activity of the drug reaches its peak after 5 to 7 hours; it usually persists for 10 to 12 hours, in some cases, however, for up to 24 hours.

Distribution

Plasma protein binding of clemastine amounts to 95%.

Biotransformation

Clemastine undergoes extensive metabolism in the liver.

Elimination

Elimination from plasma occurs biphasically, with half-lives of 3.6 ± 0.9 hours and 37 ± 16 hours. The major route of metabolite excretion (45 to 65%) is through the kidneys into urine, where only trace amounts of the parent compound are found. In lactating women, small amounts of the drug may pass into breast milk.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction at therapeutically relevant doses.

In a rat study, a reduction in pup survival, at doses more than 200X the therapeutic dose, was observed when mothers were treated through lactation.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate

Povidone

Maize Starch

Talc (acid washed)

Magnesium Stearate.

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

PVC/PVDC blister pack (50 or 60 tablets).

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Thornton & Ross Ltd.
Linthwaite,
Huddersfield,
HD7 5QH, UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 00240/0561

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

08 June 2000

10 DATE OF REVISION OF THE TEXT

20/04/2021