Global Labelling & Compliance

Tavegyl 1.0 mg

tablets clemastine (as fumarate)

Summary of Product Characteristics

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1 NAME OF THE MEDICINAL PRODUCT

Tavegyl

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Tavegyl tablet contains:

Active compounds: 1 mg of clemastine equivalent to 1.34 mg of clemastine fumarate.

Excipients: magnesium stearate, povidone, talc, maize starch, lactose monohydrate.

3 PHARMACEUTICAL FORM

Whitish circular, flat, bevelled edged tablets, on one side scored and coded "OT".

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Tavegyl is indicated for the relief of hay fever (allergic rhinoconjunctivitis) and other allergic rhinitis, urticaria of various genesis, itching, puritic dermatoses and insect stings and bites.

Tavegyl is also indicated as an adjuvant in acute and chronic eczema, contact dermatitis and drug eruptions.

4.2 Posology and method of administration

For oral administration only. The tablets should be taken with water before meals.

For adults and children over 12 years:

The usual dose is 1 tablet in the morning and 1 tablet in the evening. Unless otherwise instructed by your doctor, you should not take more than 6 tablets during 24 hours. The highest single dose is 2 tablets at one time.

For children from 6 to 12 years:
The usual dose is 1/2 to 1 tablet, which should be taken in the morning and evening.

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

4.3 Contraindications

Hypersensitivity to clemastine or other similar antihistamines or to any of the excipients.

Tavegyl should not be given to patients suffering from porphyria.

Tavegyl in tablet form should not be given to children below 6 year of age.

4.4 Special warnings and precautions for use

Use with caution in elderly patients, 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 doctor (See Posology and method of administration).

Antihistamines should be used with caution in patients with:

- epilepsy or history of seizures,
- narrow-angle glaucoma,
- stenosing peptic ulcer,
- pyloroduodenal obstruction,
- prostatic hypertrophy with urinary retention and bladder neck obstruction.

Tavegyl tablets contain lactose. Patients with rare hereditary problems of galactose intolerance, the 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 may increase the effects of other drugs that cause sedation/sleepiness (Central Nervous System (CNS) depressants, including hypnotics, Monoamine oxidase inhibitors (MAOIs), antidepressants, anxiolytics (tranquilizers), opioid analgesics; alcohol).

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

4.6 Pregnancy and lactation

Pregnancy

There is no adequate data on the use of clemastine in pregnant women. This product should not be taken during pregnancy unless the expected benefit justifies the potential risk to the foetus.

Lactation

Antihistamines may be excreted into human breast milk and may affect the nursing infant. Medicine should not be taken during breast feeding unless the potential benefits to the mother outweigh the risks to the infant.

4.7 Effects on ability to drive and use machines

Patients should be advised not to drive or operate machinery if affected by dizziness or drowsiness.

4.8 Undesirable effects

Adverse reactions are classified by frequency as follows: 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 frequency is unknown (cannot to be estimated 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 unknown but likely to be rare (≥1/10,000, <1/1,000) or very rare (<1/10,000).

System Organ Classes	**Adverse Reactions**	**Frequency**
Immune system disorders	Anaphylactic shock, Hypersensitivity reactions	Rare
Nervous system disorders	Fatigue, Sedation	Common
	Dizziness	Uncommon
	Headache, Excitability, especially in children	Rare
Cardiovascular system disorders	Tachycardia	Very rare
Respiratory, thoracic and mediastinal disorders	Dyspnoea	Rare
Gastrointestinal disorders	Abdominal pain, Nausea, Dry mouth	Rare
	Constipation	Very rare
Skin and subcutaneous tissue disorders	Skin rash	Rare

Stop taking the medicine and seek medical help immediately if you have any of the following:

- severe allergic reaction;
- dyspnea or feeling of lack of air;
- palpitations increased.

These reactions are rare.

4.9 Overdose

If you have taken more Tavegyl tablets than recommended, seek medical help or call your local toxicology center immediately.
Symptoms: the effects of antihistamine overdose may vary from Central Nervous System (CNS) depression to stimulation for example depressed level of consciousness, excitability, hallucinations, or convulsions. Anticholinergic symptoms such as dry mouth, mydriasis,

flushing, hot flashes which suffuse the face and upper body, gastrointestinal disorders, and tachycardia may also develop.

Treatment consists of elimination of the drug by gastric lavage, administration of activated charcoal and symptomatic therapy.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Mechanism of action and pharmacodynamic effects

Tavegyl (clemastine) is an H1-receptor antagonist. It belongs to the benzhydryl ether group of antihistamines, reduces capillary permeability, exerts 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, clemastine is almost completely absorbed from the gastrointestinal tract. Peak plasma concentrations are attained within 2 to 4 hours. The antihistaminic activity of the drug reaches its peak after 5 to 7 hours; it usually persists for 10 to 12 hours, and in some cases 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 safety data on clemastine fumarate have not revealed findings which are of relevance to the recommended dosage and use of the product.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Maize Starch
Talc
Povidone
Magnesium Stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years. Do not use after expiry date indicated on the package.

6.4 Special precautions for storage

Store at a temperature not exceeding 30 °C. Keep out of the reach of children.

6.5 Nature and contents of container

10 tablets in each blister packs of PVC/PVDC/Aluminium foil combined material. 2 blisters with instructions for use in each cardboard box.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

GSK Consumer Healthcare S.A., Route de l`Etraz, 1260 Nyon, Switzerland.

8 MARKETING AUTHORISATION NUMBER(S)

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT

16.03.2020