

PACKAGE LEAFLET: INFORMATION FOR THE USER

Tavegil® Tablets

Clemastine hydrogen fumarate 1.34 mg

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without a prescription. However, you still need to use Tavegil Tablets carefully to get the best results.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Tavegil Tablets are and what they are used for
2. Before you use Tavegil Tablets
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1. WHAT TAVEGIL TABLETS ARE AND WHAT THEY ARE USED FOR

Tavegil Tablets contain clemastine 1 mg as the active ingredient, which belongs to a group of antihistamines. Tavegil Tablets are used to treat:

- allergic rhinitis (inflammation of the nasal mucous membranes) including hay fever, perennial rhinitis and vasomotor rhinitis.
- allergic skin disease (dermatoses), including pruritus (intense itching), atopic eczema and contact dermatitis.
- angioneurotic oedema (rapid swelling of the skin, mucosal tissues, internal organs or brain) and drug allergy.

2. BEFORE YOU TAKE TAVEGIL TABLETS

Do not take Tavegil Tablets if you have:

- an allergy (hypersensitivity) to any of the ingredients of Tavegil Tablets (see Section 6 and Section 2 “Important information about some of the ingredients of Tavegil Tablets”),
- an allergy (hypersensitivity) to other arylalkylamine antihistamines (ask your doctor if you are unsure what these are)
- Porphyria, a metabolism disorder which affects red blood cells and may cause blistering of the skin, abdominal pains and mental problems.

Do not give Tavegil Tablets to children below one year of age.

Take special care with Tavegil Tablets if you have:

- narrow-angle glaucoma (a disease causing pressure behind the eye)
- stenosing peptic ulcer (narrowing of the upper digestive tract caused by an ulcer)
- pyloroduodenal obstruction (obstruction caused by inflammation of the intestine)
- prostatic hypertrophy with urinary retention (enlargement of the prostate gland causing bladder control problems)
- bladder neck obstruction.

Antihistamines should be used with caution in children due to the risk of excitability in this special population (see section 4)

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines, including those obtained without a prescription.

Taking Tavegil tablets may **enhance** the effects of drugs that :

- calm you (sedatives)
- induce sleep (hypnotics)
- treat depression (monoamine-oxidase inhibitors /MAOIs)

Taking Tavegil Tablets with food and drink

Like many other antihistamines, Tavegil Tablets may increase the effects of alcohol.

Do not consume alcohol whilst taking Tavegil Tablets.

Pregnancy and breast-feeding

Do not take Tavegil Tablets if you are pregnant, intending to get pregnant, or if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Tavegil Tablets may cause drowsiness and fatigue. Do not drive or operate machinery if you are affected by the tablets in this way.

Important information about some of the ingredients of Tavegil Tablets

Tavegil Tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE TAVEGIL TABLETS

Always take the medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Adults and the Elderly

Take one tablet in the morning and one tablet at night with water.

In individual cases the dose may be increased to 6 tablets daily if necessary. Your doctor will tell you if you need to increase the dose.

Children

- 1 to 3 years: take ¼ – ½ tablet (250 mcg to 500 mcg) in the morning and at night.
- 3 to 6 years: take ½ tablet (500 mcg) in the morning and at night.
- 6 to 12 years: take ½ – 1 tablet (500 mcg to 1000 mcg) in the morning and at night.

Do **not** give Tavegil Tablets to children below **one** year of age.

If you use more Tavegil Tablets than you should

Taking too many Tavegil Tablets may cause either clinical depression or central nervous system stimulation. Other symptoms such as dry mouth, fixed dilated pupils or flushing, upset stomach and rapid heart beat may also develop.

If you accidentally take too many Tavegil Tablets, or you suspect that your child has taken extra medicine, contact your doctor or hospital casualty department immediately. Take the carton and tablets with you if possible.

If you forget to take Tavegil Tablets

Take a dose as soon as you remember then go on as normal, unless it is nearly time for your next dose.

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Tavegil Tablets can cause side effects, although not everybody gets them.

STOP taking Tavegil and seek medical help **immediately** if you have any of the following which may be signs of an **allergic reaction**:

- difficulty in breathing or swallowing
- swelling of the face, lips, tongue or throat.
- severe itching of the skin, with a red rash or raised bumps.

Common side effects (affecting 1 to 10 users in 100):

Fatigue and Drowsiness.

Uncommon side effects (affecting 1 to 10 users in 1, 000):

Dizziness

Rare side effects (affecting 1 to 10 users in 10, 000):

Headache, Excitability, upset stomach, nausea, dry mouth, skin rash, allergic reactions, shortness of breath and weakness

Very rare side effects (affecting 1 user in 10, 000):

Constipation, rapid heart beat, palpitations

In general, these side-effects may lessen if the dose is reduced.

If any of the side effects gets serious, or if you have any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TAVEGIL TABLETS

Keep out of the reach and sight of children.

Do not store above 25°C. Store in the original pack.

Do not use Tavegil Tablets after the expiry 'EXP' date which is stated on the blister and the carton. The 'EXP' date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Tavegil Tablets contain

The active substance of Tavegil is clemastine (as fumarate). Each tablet contains 1 mg of clemastine.

The other ingredients are: lactose, polyvinylpyrrolidone, maize starch, talc, magnesium stearate, purified water

(for further information about the ingredients see end of Section 2)

What Tavegil Tablets look like and contents of the pack

Tavegil Tablets are white, uncoated, round tablets, 7 mm in diameter with bevelled edges, smooth on one side and marked with "OT" and scored with a single breakline on the other.

Tavegil tablets are available in:

- blister packs of 50 or 60 tablets.

Marketing Authorisation Holder and Manufacturer

Novartis Consumer Health UK Limited

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For any information about this medicinal product, please contact the Marketing Authorisation Holder.

Tavegil® is a registered Trade Mark.