

Patient Leaflet: Information for the user
Trifluoperazine 1mg and 5mg tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What 'Trifluoperazine tablets are and what are they used for
2. What you need to know before you take Trifluoperazine tablets
3. How to take Trifluoperazine tablets
4. Possible side effects
5. How to store Trifluoperazine tablets
6. Contents of the pack and other information

1. What 'Trifluoperazine tablets are and what are they used for

These tablets contain the active ingredient trifluoperazine, they are available in two strengths, 1 and 5 milligrammes (mg). Your doctor will have prescribed one strength of tablet for you. The strength will be shown on your tablet pack.

This medicine belongs to a class of drugs called phenothiazine tranquillisers. You may also hear it referred to as a neuroleptic drug. It influences the activity of certain brain cells by decreasing the effect of dopamine, a natural chemical in the brain.

At a low dosage 'Trifluoperazine' is used to manage anxiety, depression caused by anxiety and agitation. It is used in this way for short periods of time. 'Trifluoperazine' may also be used to treat nausea (feeling sick) and vomiting (being sick).

At high doses 'Trifluoperazine' is used to treat schizophrenia and related conditions. It can also be used for short periods of time to treat very bad agitation or dangerous behaviour.

2. What you need to know before you take Trifluoperazine tablets

Do not take Trifluoperazine tablets:

- If you are allergic to Trifluoperazine or any of the other ingredients of this medicine (listed in section 6).
 - If you have a liver problem, blood disorder, heart disease (such as angina or heart rhythm problems)
- This medicine will not be given to patients who are in a coma.

Warnings and precautions

Talk to your doctor or pharmacist before taking Trifluoperazine tablets if you:

- or any member of your family is suffering from any disease involving the heart and blood vessels

(cardiovascular disease) including chest pain (angina) and irregular heart beats.

- suffering from a brain disorder causing tremors, rigidity and slowing of movement (Parkinson's disease).
- suffering from fits (epilepsy).
- suffering from an eye disease called narrow angle glaucoma which causes increased pressure inside the eye, abnormal muscle weakness (Myasthenia gravis) or enlargement of prostate gland.
- exposed to extremes in temperature as this medicine can affect body temperature control.
- are an elderly person.
- suffer from loss of cognitive (memory, language, intelligence) ability - dementia.
- or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.
- Previously suffered from neuroleptic malignant syndrome (high fever, sweating, unstable blood pressure, muscle rigidity, dazed, drowsy state)
- have had a stroke or you have any of the following that can increase your risk of having a stroke.
- have a heart attack.
- have a TIA (transient ischaemic attack). This is a type of stroke where symptoms last less than 24 hours.
- have an artificial heart valve.
- have uncontrolled high blood pressure.
- have diabetes.
- have high cholesterol.
- have a family history of strokes.
- smoke.
- drink excess alcohol (this tends to weaken blood vessels and can raise blood pressure).
- have previously had to stop taking other medicines for psychiatric problems like Trifluoperazine (known as phenothiazines) because they have affected your blood cells or caused jaundice (yellowing of the skin and eyes).

In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

Even though some of the above may appear obvious, it is important that your doctor is aware if any of them apply to you.

Other medicines and Trifluoperazine tablets

Talk to your doctor or pharmacist if you are taking any other medicines. This is particularly important if you are taking the following medicines:

- Medicines to prevent fits (anticonvulsants)
- Medicines to treat Parkinson's disease (e.g. levodopa)
- Sleeping tablets
- Strong pain killers
- Medicines for high blood pressure (e.g. guanethidine)
- Anti-cholinergic medicines (e.g. atropine, procyclidine)
- Medicines for depression (e.g. other phenothiazines (e.g. prochlorperazine), lithium)
- Medicines which reduce white blood cell production
- Metrizamide (used in radiology for spinal cord and brain examinations)
- Desferrioxamine (used to treat iron poisoning)
- Medicines to thin your blood (anticoagulants)
- Antacids used to treat indigestion

You should also tell your doctor or dentist if you are taking ‘Trifluoperazine’ before being given an anaesthetic.

Medicines such as ‘Trifluoperazine’ may affect the way your body helps to keep you warm (e.g. shivering) or cool (e.g. sweating). Be careful at extremes of temperature.

Trifluoperazine tablets with food, drink and alcohol

You should not drink alcohol while you are taking these tablets.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The following symptoms may occur in newborn babies, of mothers that have used Trifluoperazine in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Driving and using machines

‘Trifluoperazine’ may cause drowsiness, dizziness and blurred vision. Take care if you are driving, operating machinery or doing other activities where you need to be alert. You should not do any of these activities if you experience any of these effects; if you suffer badly tell your doctor.

Trifluoperazine tablets contains 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 Trifluoperazine tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Swallow your tablets without chewing them, you can drink a glass of water if you wish. The dose of Trifluoperazine’ which your doctor prescribes will depend on your symptoms.

The recommended dose is:

The usual dose of ‘Trifluoperazine’ is shown in the table below:

Patient Type	Low dosage For the treatment of anxiety or nausea and vomiting	High dosage For the control of schizophrenia and related conditions
Adults	The usual total dose is 2 mg to 6 mg a day	The usual dose is 10 mg to 15 mg a day. Further increases in your dose may be made at minimum intervals of 3 days.
Elderly (over 65 years of age)	The starting dose of ‘Trifluoperazine’ should be no more than half that of adult patients	The starting dose of ‘Trifluoperazine’ should be no more than half that of adult patients.
Children	For children aged 6-12 years the dose is no more than 4 mg a day	For children aged under 12 years the starting dose is no more than 5 mg a day

You will usually need to take your medicine twice or three times a day depending on the dose your doctor has prescribed. Your doctor or pharmacist will tell you when you should take it.

Doctors sometimes prescribe different doses to those given above. If this applies to you discuss it with your doctor if you have not already done so.

The pharmacist's label on your pack will tell you how much your doctor would like you to take.

Please read the label carefully.

Do not take more than your doctor has recommended.

It is important to follow your doctor's instructions. For mood disorders and schizophrenia, it may take several weeks for you to feel the full benefit of this medicine.

If you take more Trifluoperazine tablets than you should

You should only take the dose that your doctor or pharmacist has told you. If you take too many tablets, contact your doctor or hospital casualty department straight away. Take your tablet pack with you.

If you forget to take Trifluoperazine tablets

Leave out that dose completely. Take your next dose of 'Trifluoperazine' at the normal time.

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

If you stop taking Trifluoperazine tablets

If you stop your treatment suddenly, your symptoms may come back. Nausea, vomiting, insomnia and involuntary movement disorders have also been reported. To help prevent this, it is best to gradually reduce the treatment.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any below serious side effects, stop taking Trifluoperazine Tablets immediately and contact your doctor straight away.

- Blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.
- Signs of serious abnormal or irregular heart rhythms or abnormal ECG heart tracing.
- Skin rashes (including increased sensitivity to the sun).
- Patients taking 'Trifluoperazine' develop an unusual reaction, even though they may have been taking it for some time. Symptoms of this reaction are a high temperature, rigid muscles, drowsiness and occasional loss of consciousness. This is called Neuroleptic Malignant Syndrome and requires emergency admission to hospital for treatment.

Other side effects are:

Rare: may affect up to 1 in 1,000 people

Medicines such as 'Trifluoperazine' can have effects on muscle control. If this happens symptoms can include slurred speech, odd movements of the face, particularly of the tongue, eyes, head or neck (such as twisting of the neck which causes an unnatural positioning of the head), rigid muscles, tremors or restlessness and difficulty in sitting still.

Very rare: may affect up to 1 in 10,000 people

- Fast heartbeat
- Constipation
- Difficulty in passing urine
- High temperature
- Jaundice (yellowing of the skin and eyes)
- Eye problems
- Skin colouring (pigmentation)
- Blood problems. If you get a bad sore throat or high fever or become very tired and pale or you notice bruises and nose bleeds tell your doctor.

Not known: frequency cannot be estimated from the available data

- 'Trifluoperazine' may affect certain types of breast cancers, or lead to breast enlargement in men or to inappropriate milk production or altered menstrual cycle (e.g. periods stop).
- Physical or mental tiredness or lack of energy.
- Loss of appetite
- Weight gain
- Drowsiness,
- Dizziness
- Restlessness,
- Difficulty in sleeping
- Blurred vision,
- Faintness on standing up
- Dry mouth
- Muscle weakness
- Water retention
- Confusion.
- Occasionally some patients have complained of feeling dulled, whilst others of being agitated.
- Some patients (especially those on high doses of 'Trifluoperazine') experience problems with muscle control, which may continue for years. Such patients may experience constant chewing or tongue movements or other gentle movements of the head, neck or trunk. Uncontrollable movements of the arms and legs have also been reported in these patients. If these effects occur tell your doctor straight away.

Nausea, vomiting, insomnia and involuntary muscle disorders are all possible if treatment is suddenly stopped.

Your doctor should check your progress regularly, if you are on 'Trifluoperazine' for a long time, to make sure no unwanted effects are developing.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 or search for MHRA yellow card in the Google play or Apple App Store.

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

5. How to store Trifluoperazine tablets

- Keep this medicine out of the sight and reach of children
- Do not use this medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.
- Keep the tablets in a dry place and do not store above 25°C and protect from light by keeping in their original pack.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Trifluoperazine tablets contains

- The active substance is Trifluoperazine.
- The other ingredients are Starch, lactose, povidone, magnesium stearate, talc, Opaseal, sucrose, titanium dioxide E171 and Opalux blue which contains E132.

What Trifluoperazine tablets looks like and contents of the pack

'Trifluoperazine' Tablets are available in packs of 50, 100, 250, 500, 1000 tablets.

Marketing Authorisation Holder

Advanz Pharma Generics (UK) Limited,
Dashwood House, 69 Old Broad Street,
London, EC2M 1QS, United Kingdom

Manufacturer

Customs Pharmaceuticals Limited,
Tecore house, Conway Street,
Hove, East Sussex BN3 3LW,
UK.

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

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