

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Trifluoperazine 5mg/5ml Oral Solution

Trifluoperazine Hydrochloride

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 Oral Solution is and what it is used for
2. What you need to know before you take Trifluoperazine Oral Solution
3. How to take Trifluoperazine Oral Solution
4. Possible side effects
5. How to store Trifluoperazine Oral Solution
6. Contents of the pack and other information

1. What Trifluoperazine Oral Solution is and what it is used for

Trifluoperazine 5mg/5ml Oral solution contains the active ingredient trifluoperazine present as hydrochloride, which belongs to a class of drugs called phenothiazine tranquilisers, also 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 dose, Trifluoperazine Oral solution is used to manage anxiety and depression. It is used in this way for short periods of time. Trifluoperazine 5mg/5ml Oral solution may also be used to treat nausea (feeling sick) and vomiting (being sick).
- At high doses, Trifluoperazine Oral solution is used to treat and prevent relapses of schizophrenia (a serious mental illness). It can also be used for short periods of time to treat bad agitation or dangerous behaviour.

2. What you need to know before you take Trifluoperazine Oral Solution

Do not take Trifluoperazine Oral Solution:

- If you are allergic to trifluoperazine hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- If you are suffering from liver problems, blood disease, inability of the heart to maintain adequate circulation causing breathlessness and swelling of the ankles.
- If you 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 or eyes). Ask your doctor about this.

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 Oral Solution if you are:

- 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

- suffering from abnormal muscle weakness (Myasthenia gravis)
- suffering from an enlargement of prostate gland
- exposed to extremes in temperature as this medicine can affect body temperature control
- an elderly person
- 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.
- suffering from loss of cognitive (memory, language, intelligence) ability - dementia.
- if you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.
- if you have had a stroke or have any of the following that can increase your risk of having a stroke (e.g. heart attack, uncontrolled high blood pressure, diabetes, family history of strokes, you smoke or drink excess alcohol).

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 Oral Solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

The effects of these medicines may change, especially if you are taking:

- sleeping tablets,
- strong pain killers (e.g. codeine)
- medicines which result in lowering of blood pressure (e.g. guanethidine)
- anticholinergic medicines used to reduce saliva and lung secretions (e.g. atropine, procyclidine)
- antidepressants (e.g. other phenothiazines, lithium)
- medicines for fits (anticonvulsants)
- medicines for Parkinson's disease (e.g. levodopa)
- blood thinning medicines (anticoagulants such as warfarin)
- medicines used to treat iron poisoning (desferrioxamine)
- antacids used to treat indigestion.
- medicines for psychiatric conditions (neuroleptics)
- heart medicines which prolong the QT interval (e.g. quinidine, disopyramide, procainamide, amiodarone, sotalol)
- drugs causing electrolyte imbalances (e.g. diuretics)

You should tell your doctor or dentist that you are taking Trifluoperazine before being given an anaesthetic.

Trifluoperazine Oral Solution with food, drink and alcohol

You should not drink alcohol whilst you are taking this medicine. This medicine can be taken with or without food.

Pregnancy, breast-feeding & 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.

. It is particularly important not to take Trifluoperazine Oral Solution during the first three months of pregnancy.

Ask your doctor or pharmacist for advice before taking any 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 5mg/5ml Oral Solution may make you feel drowsy or dizzy or give you blurred vision. You should not drive or use machines when you first start to take this medicine until you are certain that you are not getting these side effects. If in any doubt, speak to your doctor before you drive or use machines.

Trifluoperazine 5mg/5ml Oral Solution contains sodium, ethanol, sodium benzoate, propylene glycol and benzyl alcohol.

This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially ‘sodium-free’.

This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per 25 ml.

This medicine contains 1 mg sodium benzoate in each ml.

This medicine contains 100.95 mg propylene glycol in each ml.

If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol.

If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

This medicine contains 0.0257 mg benzyl alcohol in each ml.

Benzyl alcohol may cause allergic reactions.

Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

3. How to take Trifluoperazine Oral Solution

Always take this medicine exactly as your doctor or pharmacist has told you. The pharmacist’s label on your pack will tell you how much and how often you should take your oral solution. Please read the label carefully. You should check with your doctor or pharmacist if you are not sure. Do not take more than your doctor has recommended.

Your doctor will decide on a suitable dose depending on your condition. The usual dose is shown in the table below. You will usually need to take your medicine twice or three times a day, depending on the dose your doctor has chosen for you.

The recommended dose is:

Remember each 5ml of oral solution contains 5mg of “Trifluoperazine”

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 dose is 2 mg to 6mg a day	High dose in adults is 5-25mg a day in divided doses
Elderly (over 65 years of age)	The starting dose of oral solution should be no more than half that of adult patients	The starting dose of oral solution should be no more than half that of adult patients
Children	For children aged 3-5 years, the dose is no more than 1mg a day. For children aged 6-12 years the dose is no more than 4mg a day.	High dose in children (aged 6-12 years) is 5mg in divided doses.

During treatment your doctor should regularly check you for physical side effects, changes in your blood counts or liver function, and any heart problem, especially if you taking this medicine for a long time or are also taking other medicines.

Method of administration

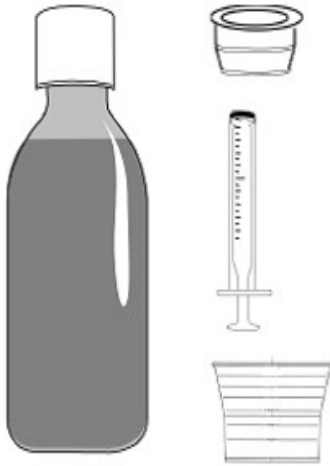
Oral use

A graduated oral syringe, a Press-In bottle Adaptor and a graduated dosing cup are provided with the product.

Instructions for using the oral syringe and the dosing cup

Please read these instructions carefully before taking the medicine. This will help you to use the oral syringe and the dosing cup correctly.

What you will be using



A press in bottle adaptor:

- that you insert into the neck of the bottle (only if you are going to use the oral dosing syringe to measure your dose).
- once you have inserted it, do not remove it.

A bottle containing the medicine:

- that has a child-resistant screw cap.
- always screw the cap back on after use.

An oral dosing syringe:

- that consists of a clear plastic tube with a plunger inside.
- the oral syringe fits into the bottle adaptor and is used to measure out the required amount of medicine from the bottle (for doses below 10ml).
- use a new bottle adaptor and oral dosing syringe each time you start a new bottle of medicine.

A dosing cup:

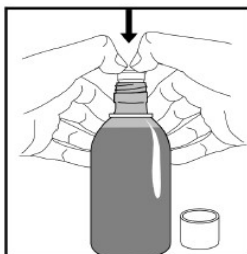
- That should be used if the prescribed dose is 10ml or more.
- If you are going to use the cup to measure your dose, do not insert the adaptor into the neck of the bottle.
- Empty the required dose of medicine into the dosing cup and then check the total volume of solution.
- Drink the entire solution right away.

To clean the cup:

- rinse the cup with clean water
- dry the cup with a clean tissue and place it back over the cap of the bottle.

If you are going to use the oral dosing syringe to measure your dose:

Fitting the press in bottle adaptor into a new bottle of medicine



1. Remove the cap from the bottle by pushing it down firmly and turning it anti-clockwise (as shown on the top of the cap).
2. Holding the open bottle upright on a table, push the bottle adaptor firmly into the neck of the bottle as far as it will go.

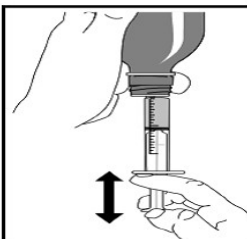
Note: You may not be able to push the bottle adaptor down fully but this does not matter as it will be forced into the bottle when you screw the cap back on.

3. screw the cap back on the bottle.

Preparing a dose of medicine



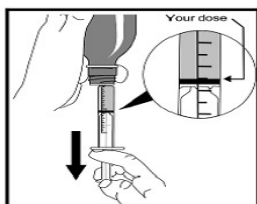
4. Remove the cap from the bottle by pushing it down firmly and turning it anti-clockwise (as shown on the top of the cap).
5. Check that the plunger is pushed fully into the oral syringe.



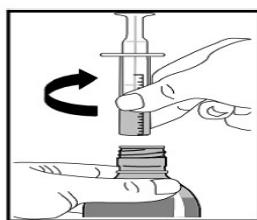
6. Keeping the bottle upright, insert the oral syringe firmly into the bottle adapter.
7. Holding the oral syringe in place, carefully turn the bottle and oral syringe upside down.
8. Before you measure your dose you need to get rid of any large bubbles that may be trapped in the oral syringe. To do this:
 - slowly pull the plunger all the way out so that the oral syringe fills with medicine.
 - then, push the plunger all the way back in so that it is empty again.

Measuring a dose of medicine

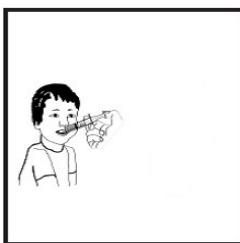
Note: The total amount of solution that can be measured into the oral syringe is 5 ml. Depending on the prescribed dose, it may be necessary to repeat steps 10 to 15. For example, if the prescribed dose is 7.5 ml, it will be necessary to measure out the solution in two separate stages: 5 ml + 2.5 ml.



9. Find the marker on the oral syringe that corresponds to the required amount of medicine.
10. Slowly pull the plunger out until the top edge of the black ring inside is exactly level with the marker.
11. Carefully turn the bottle and oral syringe back upright.



12. Remove the oral syringe from the bottle adapter by gently twisting it out.



Taking the medicine

13. Sit upright.
14. Put the end of the oral syringe into the mouth.
15. Slowly push the plunger in and swallow the medicine directly from the oral syringe.

16. Replace the child-resistant screw cap after use.
17. To clean the oral syringe:
 - Rinse the syringe by drawing water into the syringe and pushing the syringe plunger to the bottom of the syringe barrel, at least three times.
 - Do this after each time that you use the oral syringe.

If you take more Trifluoperazine Oral Solution than you should

If you think that you, or any other person, have taken too much oral solution, contact your doctor or hospital casualty department immediately. Take this leaflet and any remaining oral solution with you so that the medical staff know exactly what you have taken.

If you forget to take Trifluoperazine Oral Solution

If you miss a dose, wait until your next dose. Do not take the dose you have missed. You can then carry on as before. Do not take more than one dose at a time.

If you stop taking Trifluoperazine Oral Solution

Continue to take Trifluoperazine Oral Solution even if you no longer feel ill. Do not stop taking this medicine without talking with your doctor first, especially if you have taken large doses for a long time. When the time comes to stop your doctor will probably decrease your dose gradually as stopping the oral solution suddenly may cause ill-effects such as nausea (feeling sick), vomiting (being sick), sweating and difficulty in sleeping.

For mood disorders and schizophrenia, it may take several weeks for you to feel the full benefit of this medicine. If you stop taking this medicine suddenly, your symptoms may come back.

4. Possible side effects

Like all medicines, this medicine can sometimes cause side effects, although not everybody gets them. If you notice any of these symptoms seek medical advice immediately.

If you experience any below serious side effects, tell your doctor immediately:

- 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.
- Abnormal heart rhythms including a life-threatening irregular heart beat called torsades de pointes or abnormal ECG heart tracing or heart stopping (cardiac arrest) and unexplained death.
- Patients may develop Neuroleptic Malignant Syndrome. This causes a high temperature, rigid muscles, drowsiness, occasional loss of consciousness, and requires emergency admission to hospital for treatment.
- 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.

Other side effects are:

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

• Medicines such as Trifluoperazine Oral Solution 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 heart beat,
- Constipation,
- Difficulty or inability to pass urine
- High temperature.
- Jaundice (yellowing of skin and whites of eyes),
- Eye problems
- Skin colouring (pigmentation)
- Blood problems.

if you suffer from a sore throat, high fever, feel very tired, become pale, develop bruises and nose bleeds. These may indicate blood problems developing as a result of using this medicine.

Not known: frequency cannot be estimated from the available data

- Trifluoperazine Oral Solution can 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).
- Some patients (especially on high doses of this medicine) 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 neck, head or trunk. Uncontrollable movements of the arms and legs have also been reported in these patients.

- Occasionally, some patients have complained of feeling slowed down, whilst others of being agitated.
- Some patients may also experience weakness, drowsiness, dizziness, restlessness, difficulty in sleeping, dry mouth, blurred vision, muscle weakness, loss of appetite, faintness on standing up, skin rashes (including increased sensitivity to the sun), weight gain, water retention causing swelling or confusion.

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 Oral Solution to make sure no unwanted effects are developing.

If any of the side effects become serious, or if you notice 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 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 Oral Solution

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 carton and bottle label after 'Exp'. The expiry date refers to the last day of that month.

Once the bottle is opened use within 2 months.

Keep bottle in the original carton to protect from light.

Do not throw away medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Trifluoperazine Oral Solution contains

The active substance in Trifluoperazine 5mg/5ml Oral Solution is trifluoperazine hydrochloride. Each 5ml of Oral solution contains 5mg trifluoperazine present as hydrochloride.

The other ingredients are: sodium benzoate, propylene glycol, citric acid anhydrous, sodium citrate, sucralose, orange flavour (SP 14104/04) (including propylene glycol, ethanol, benzyl alcohol), natracol curcumin (E100) (including propylene glycol), citric acid and purified water.

What Trifluoperazine Oral Solution looks like and contents of the pack

Trifluoperazine Oral solution is a clear, yellow coloured solution with characteristic orange odour. It is available in an amber glass bottle containing 150 ml of medicine. This pack also contains a 5 ml plastic oral dosing syringe with 0.1 ml graduations, an adapter and 20 ml dosing cup.

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The marketing authorisation holder will ensure that the package information leaflet is made available on request from patient's organisations in formats appropriate for the blind and partially-sighted. Contact Number: 44 (0) 8700 70 30 33

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