

#### Not known: frequency cannot be estimated from the available data

- 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**.
- Trifluoperazine can affect certain types of breast cancers, lead to breast enlargement in men, 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.
  - 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.
  - Some patients may also experience weakness, drowsiness, dizziness, restlessness, difficulty in sleeping, dry mouth or 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.
- In newborn babies, of mothers that have used Trifluoperazine in the last trimester (last three months of their pregnancy) symptoms such as shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems and difficulty in feeding, may occur.

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 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](http://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 Solution

- Keep this medicine out of the sight and reach of children
- Store below 25°C. Store in the original package in order to protect from light
- Take back any remaining solution to the pharmacy 1 month after you first open it
- Do not use this medicine after the expiry date which is stated on the label and carton (exp: month, year)
- The expiry date refers to the last day of that month
- Do not use this medicine if you notice that the appearance or smell of your medicine has changed. Talk to your pharmacist
- Do not throw away any medicines via wastewater 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 Solution contains

- The active ingredient is trifluoperazine hydrochloride
- The other ingredients are methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), propylene glycol (E1520), sorbitol solution 70% (E420), liquid maltitol (E965), lime flavour, aniseed flavour, caramel E150 and purified water.

#### What Trifluoperazine Solution looks like and contents of the pack

A pale brown syrup with an odour of aniseed and lime.

It comes in a brown glass bottle holding 150ml of solution.

#### Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

This leaflet was last revised in 09/2021



## Package leaflet: Information for the user

### Trifluoperazine 5mg/5ml Oral Solution

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

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

The name of your medicine is Trifluoperazine 5mg/5ml Oral Solution (referred to as Trifluoperazine Solution in this leaflet). It contains trifluoperazine hydrochloride. This belongs to a group of medicines called phenothiazines.

Trifluoperazine can be used to treat:

- schizophrenia
- behavioural problems
- feeling and being sick
- or to calm your emotions particularly if you feel anxious, agitated, paranoid depressed.

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

#### Do not take Trifluoperazine Solution if:

- you are allergic (hypersensitive) to trifluoperazine (or medicines like trifluoperazine) or any other ingredients in this liquid (listed in section 6). The signs of allergic reaction can include a rash, itching or shortness of breath
- you are pregnant or breast-feeding
- you have a history of or currently have blood problems, inability of the heart to maintain adequate circulation causing breathlessness and swelling of the ankles
- you have liver problems
- you have heart failure
- you have previously had to stop taking other medicines for psychiatric problems like Trifluoperazine because they have affected your blood cells or caused jaundice (yellowing of the skin and eyes) Ask your doctor about this
- you are having a special X-ray examination of the brain or spinal cord involving a chemical called metrizamide (your doctor will be able to help you).
- you suffer from any abnormality of the blood cells or are taking medicines which can reduce blood cells.

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Trifluoperazine Solution.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Trifluoperazine Solution, if:

- you have heart problems including unusual heart beats, heart and blood vessels disease (cardiovascular disease), heart failure or angina
- you have Parkinson's Disease
- you have epilepsy
- you have or have had in the past narrow angle glaucoma (this is abnormal pressure in the eye accompanied by pain and blurred vision)
- you have a condition that causes muscle weakness with tiredness, called myasthenia gravis
- you have an enlarged prostate gland
- if you are an elderly person
- if you are suffering from loss of cognitive ability (memory, language, intelligence), such as dementia

- 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 previously suffered from neuroleptic malignant syndrome (high fever, sweating, unstable blood pressure, muscle rigidity, dazed, drowsy state)
- you have had a stroke or you have any of the following that can increase your risk of having a stroke
  - a heart attack
  - a TIA (transient ischaemic attack). This is a type of stroke where symptoms last less than 24 hours
  - an artificial heart valve
    - uncontrolled high blood pressure
    - diabetes
    - high cholesterol
    - a family history of strokes
    - you smoke
    - you drink excess alcohol (this tends to weaken blood vessels and can raise blood pressure).

Trifluoperazine may affect the way your body helps to keep you warm (shivering) or cool (sweating). Be careful at extremes of temperature.

**Other important information to take into account before you take this medicine:**

- if you or members of your family have heart problems (including heart failure, heart attack or uneven heart beats) or you have low potassium or magnesium in your blood, your doctor may do some tests on your heart and blood before giving you this medicine.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Trifluoperazine Solution.

**Other medicines and Trifluoperazine 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, including herbal medicines. The effects of these medicines may change, especially if you are taking:

- medicines that help you sleep such as temazepam
- anaesthetics used prior to surgery
- strong painkillers such as codeine
- medicines to treat high blood pressure such as guanethidine
- anticholinergic medicines used to reduce saliva and lung secretions such as atropine, procyclidine
- heart medicines such as quinidine, disopyramide, procainamide, amiodarone, sotalol, dofetilide, bretylium
- desferrioxamine, used to treat some types of anaemia, a type of blood problem
- medicines that affect electrolytes such as diuretics (water tablets)
- levodopa, used to treat Parkinson's disease
- metrizamide, used when you are having scans at the hospital (radiography)
- medicines to treat mental illness and depression such as other phenothiazines, lithium
- medicines for fits (anticonvulsants)
- medicines to thin your blood (anticoagulants) such as warfarin
- medicines to treat heartburn or indigestion
- medicines for psychiatric conditions such as neuroleptics.

**Trifluoperazine Solution with food, drink and alcohol**

You must not drink alcohol whilst taking this medicine. This is because this medicine may make you feel drowsy and drinking alcohol will make you even more drowsy. Drinking alcohol may also affect the condition you are suffering from.

**Pregnancy and breast-feeding:**

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. You should not use this medicine if you are pregnant or breast-feeding unless your doctor feels it is absolutely necessary.

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 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 you have any doubts, talk to your doctor before you drive or use machines.

**Important information about what is in this medicine:**

Trifluoperazine Solution contains:

- methyl (E218) and propyl hydroxybenzoates (E216). May cause allergic reactions (possibly delayed).
- liquid maltitol (E965). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- sorbitol (E420). This medicine contains 650 mg sorbitol in each 5ml dose. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.
- propylene glycol (E1520). This medicine contains 77.7 mg propylene glycol in each 5 ml dose.

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### 3. How to take Trifluoperazine Solution

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

**Taking this medicine**

- this medicine contains 5mg of trifluoperazine in each 5ml
- take this medicine by mouth
  - if you feel that the effect of your medicine is too strong or too weak, do not change the dose yourself, but talk to your doctor or pharmacist.

**Adults**

- The usual dose ranges from 2mg to 15mg daily in divided doses
- You will start treatment on a low dose and will be increased as necessary by your doctor
- Older people will need to start on a lower dose as you may be more sensitive to the effects of the medicine. Your doctor will gradually increase this dose.

**Children**

**Low Dose**

- Children aged 3 to 5 years: up to 1mg a day. You should split this dose over the day
- Children aged 6 to 12 years: up to 4mg a day. You should split this dose over the day

**High dose**

- Children under 12 years of age: up to 5mg a day. You should split this dose over the day. Your doctor may increase this dose.

**If you take more Trifluoperazine Solution than you should**

Talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken. Signs of an overdose may include difficulty with movement and low blood pressure which may make you feel dizzy when standing up.

**If you forget to take Trifluoperazine Solution**

- Do not take a double dose (two doses at the same time) to make up for forgotten doses.
- Skip the missed dose then go on as before.

**If you stop taking Trifluoperazine Solution**

Keep taking Trifluoperazine solution until your doctor tells you to stop. The doctor will lower your dose gradually.

If you stop taking the medicine suddenly you may get withdrawal symptoms. Signs include:

- feeling or being sick, sweating and difficulty in sleeping (insomnia)
- your original symptoms becoming worse
- movements that you can't control.

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

### 4. Possible side effects

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

**Stop taking the medicine straight away and see your doctor if:**

- **you have an allergic reaction to trifluoperazine solution**  
An allergic reaction may include any kind of skin rash, flaking skin, boils or sore lips and mouth, sudden wheezing, fluttering or tightness of the chest or collapse.
- **you have any of the following symptoms:**
  - unusually fast heart beat, unstable blood pressure (feeling dizzy, light-headed or faint) and sweating. These are early warning signs of a disorder caused by the type of medicine you are taking
  - very high body temperature, muscle stiffness or a change in consciousness leading to coma.

**Other side effects are:**

Tell your doctor straight away if you notice any of the following serious side effects:

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

- 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.
- If you have chest pain (angina) and your pain is getting worse. Abnormal heart rhythms including a life-threatening irregular heart beat called torsades de pointes, abnormal ECG heart tracing or heart stopping (cardiac arrest) and unexplained death.

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

- Patients may also experience a fast or irregular heartbeat.
- Constipation, difficulty or inability to pass urine or a high temperature.
- Jaundice (yellowing of skin and whites of eyes), eye problems or skin colouring (pigmentation).
- If you suffer from a sore throat, high fever, feel very tired, become pale, develop bruises and nose bleeds. These may indicate developing blood problems as a result of using this medicine.

*Continued overleaf*