

## 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
- you have liver problems
- you have heart failure.

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 disease or 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
- 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
- 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

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- 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. This includes medicines you buy without a prescription, including herbal medicines. This is because trifluoperazine can affect the way some other medicines work. Also some medicines can affect the way trifluoperazine works.

Tell your doctor if you are taking any of these medicines:

- 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 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 and propyl parahydroxybenzoates. These may cause an allergic reaction. This allergy may happen some time after starting the medicine
- sorbitol and liquid maltitol. If your doctor has told you that you cannot tolerate some sugars, see your doctor before taking this medicine.

### 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.

#### If you get any of the following side effects, see your doctor as soon as possible:

- 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**
- feeling agitated, confused or over-excited
- blood problems. You may notice signs such as high temperature or chills, sore throat, ulcers in your mouth or throat and unusual tiredness
- heart changes including fast heart beats, unusual heart beats, heart attack. Symptoms of a heart attack are chest pain which may spread to the shoulders, neck or arms and shortness of breath. If you get these see a doctor straight away. Unexplained deaths have been reported but it is not proven that they were caused by trifluoperazine
- low blood pressure. You may feel dizzy when standing up

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- yellowing of the skin and whites of your eyes (jaundice)
- unusual movements, often of the mouth, lips, eyes and tongue. These movements can also include trembling and shaking of the hands and feet, twisting of the body, shuffling walk and stiffness of the arms and legs and unable to sit still
- blurred vision, eye changes such as clouding of the lens or purple colouring of the skin
- repeated infections. Your doctor may want to perform some tests
- symptoms coming back if you have breast cancer.

**Tell your doctor if you get any of these side effects:**

- feeling tired, drowsy or dizzy
- unable to sleep, feeling restless
- dry mouth
- fever
- skin rashes, skin reaction to direct sunlight
- swelling of the breasts (particularly in men) and breast milk production
- light periods or absence of periods
- weight gain, loss of appetite
- muscle weakness
- water retention, difficulty in passing water (urine)
- constipation
- changes in your level of alertness
- sleep walking, particularly if you are taking lithium at the same time as trifluoperazine.

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.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

**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 01/2018**