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.

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 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 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

3. How to take Trifluoperazine Solution
This leaflet is written for the information of the patient. It does not take the place of medical advice. It is important that you take this medicine exactly as your doctor recommends. The total amount of medicine you take daily may be divided into several doses. Take it at regular times each day. It does not matter if you take it with or without food.

4. Possible side effects
The most common side effects of this medicine are:
- 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.

5. How to store Trifluoperazine Solution
Keep this medicine out of the sight and reach of children
Store below 25°C. 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), ascorbic acid (E330), lime flavour, anised flavour, caramel E110 and purified water.

What Trifluoperazine Solution looks like and contents of the pack
A pale brown syrup with an odour of anised 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 11/2015
PGB10

Tell your doctor if you get any of these side effects:
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Reporting of side effects
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By reporting side effects you can help provide more information on the safety of this medicine.

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- 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.

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, itching skin, boils or sore lips and mouth, sudden wheezing, flattening 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 beat, 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

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