

TRIFLUOPERAZINE

1 mg & 5 mg TABLETS

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

THIS LEAFLET CONTAINS

1. What Trifluoperazine is for
2. Before you take Trifluoperazine
3. How to take Trifluoperazine
4. Possible side effects
5. How to store Trifluoperazine
6. Further information

1. WHAT TRIFLUOPERAZINE IS FOR

The name of your medicine is Trifluoperazine. It contains the active ingredient trifluoperazine hydrochloride. This belongs to a group of medicines called phenothiazines.

Trifluoperazine tablets can be used to treat:

- schizophrenia
- behavioural problems
- feeling or being sick
- or to calm your emotions particularly if you feel anxious, agitated, over-excited, violent or dangerously impulsive.

If you are not sure why you have been prescribed this medicine then please ask your doctor.

2. BEFORE YOU TAKE TRIFLUOPERAZINE

Do not take Trifluoperazine and tell your doctor if you:

- are allergic to trifluoperazine, other phenothiazines (such as prochlorperazine or chlorpromazine) or any other ingredient in trifluoperazine tablets (listed in section 6 of this leaflet). The signs of an allergic reaction can include a rash, itching or shortness of breath
- have any blood problems, such as a low number of blood cells (bone marrow depression)
- have liver problems
- have a tumour of your adrenal gland that causes high blood pressure (phaeochromocytoma)
- have dulled senses such as feeling sleepy or uncoordinated, have blurred vision, slurred speech or are less aware of your surroundings (CNS depression).

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.

Take special care with Trifluoperazine

Tell your doctor before you take this medicine if you:

- have heart problems including unusual heart beats, heart disease or heart failure
- have lung and breathing problems
- have kidney problems
- have or have had yellowing of the skin or whites of the eyes (jaundice)
- have Parkinson's disease
- have or have had narrow angle glaucoma (this is abnormal pressure in the eye accompanied by pain and blurred vision)
- have an enlarged prostate gland
- have epilepsy or have had fits (seizures) in the past
- have a condition that causes muscle weakness with tiredness, called myasthenia gravis
- have an underactive thyroid gland
- are feeling depressed
- have had a stroke or 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 or drink excess alcohol.

- If you, or anyone else in your family, have a history of blood clots, as medicines like trifluoperazine have been associated with the formation of blood clots.
- The elderly should take Trifluoperazine with caution in very hot or cold weather. This is because this medicine may cause a higher body temperature than usual in hot weather (hyperthermia) and a lower body temperature in cold weather (hypothermia)
- If you are going to be given an anaesthetic, tell your doctor or dentist that you are taking Trifluoperazine.

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 levels of calcium, potassium or magnesium in your blood, your doctor may do some tests on your heart and blood before giving you this medicine
- your doctor may also want to give you regular blood tests in the first few months of your treatment
- do not go into direct sunlight if you are taking high doses of this medicine. This is because you may become more sensitive to strong sunlight while taking this medicine
- do not put this medicine in contact with your skin as it may cause a skin rash with itching. If the medicine does have contact with your skin, wash the area thoroughly.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking or have recently taken **any** other medicines, including medicines bought without a prescription. This is because Trifluoperazine can affect the way some other medicines work. Also some medicines can affect the way Trifluoperazine works.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- heart medicines such as quinidine, disopyramide, procainamide, amiodarone, sotalol, dofetilide, calcium channel blockers such as verapamil, ACE inhibitors such as captopril
- medicines to treat high blood pressure such as propranolol, guanethidine, methyl dopa, minoxidil, clonidine
- medicines that control your emotions such as anxiety medicines, antidepressants (such as amitriptyline), pimozone, sertindole, haloperidol, lithium, trazodone
- medicines that help you sleep such as sedatives or hypnotics such as temazepam
- medicines to treat epilepsy such as barbiturates, phenytoin, primidone, carbamazepine, oxcarbazepine, ethosuximide, valproate
- medicines to treat malaria such as quinine, artemether and lumefantrine
- antibiotics such as sparfloxacin, moxifloxacin and intravenous erythromycin
- medicines to treat Parkinson's disease such as levodopa, bromocriptine, amantadine, pergolide and trihexyphenidyl
- memantine to treat Alzheimer's disease
- medicines to treat allergies such as hayfever (antihistamines) for example terfenadine and astemizole
- medicines to treat stomach problems such as cimetidine or cisapride
- medicines to treat diabetes such as gliclazide or tolbutamide
- strong painkillers such as codeine, tramadol or methadone
- medicines to treat cancer
- tetrabenazine to treat disorders that cause unnatural movements
- medicines that help the body get rid of water and affect electrolyte balance (diuretics) such as furosemide
- metoclopramide or droperidol to treat nausea (feeling sick) and vomiting
- desferrioxamine to treat some types of anaemia, a type of blood problem
- atomoxetine, amphetamine or dexamfetamine to treat Attention Deficit Hyperactive Disorder (ADHD)
- adrenaline to treat allergic reactions or cardiac arrest
- ritonavir to treat viral infections
- pentamidine isetionate to treat lung infections
- sibutramine to help you lose weight
- kaolin to treat diarrhoea
- antacids to treat indigestion or heartburn. You should take these at least two hours after taking Trifluoperazine.

Taking Trifluoperazine tablets with food and drink

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 cause serious breathing problems.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, planning to become pregnant or are breast-feeding. 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

Do not drive or use tools or machines if this medicine makes you drowsy or if it has affected your eyesight.

Important information about some of the ingredients of Trifluoperazine

This medicine contains **lactose** and **sucrose** (type of sugars). If your doctor has told you that you cannot tolerate some sugars, check with your doctor before taking this medicine.

3. HOW TO TAKE TRIFLUOPERAZINE

Always take Trifluoperazine tablets exactly as your doctor has told you. Take this medicine by mouth.

Adults

- The usual dose for adults is 2 mg to 15 mg daily in divided doses
- The dose prescribed and how often you should take the doses will depend upon the condition being treated and on your response. You will start treatment on a low dose which will be increased as necessary by your doctor
- Elderly patients 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 your dose.

Children

Low dose

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

High dose

- Children under 12 years of age: up to 5 mg a day. You should split this dose over the day. The doctor may increase this dose depending on the child's age, weight and symptoms.

If you take more Trifluoperazine than you should

Talk to a doctor to 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 drowsiness, low body temperature, low blood pressure, twisting of your limbs, stiffness, shaking, unusual heart beats and coma

If you forget to take Trifluoperazine

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

If you stop taking Trifluoperazine

Keep taking Trifluoperazine 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 and difficulty sleeping (insomnia)
- your original symptoms becoming worse
- movements that you cannot 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** an allergic reaction may include any kind of skin rash, flaking skin, red and raised lumps (hives), joint pain, fever, sore lips and mouth, sudden wheezing, fluttering or tightness of your chest or collapse
- **have any of the following symptoms:** unusually fast heart beat, unstable blood pressure (feeling dizzy, light-headed or faint), sweating, very high body temperature, muscle stiffness or a change in consciousness leading to coma. These are warning signs of a disorder called **neuroleptic malignant syndrome**
- **have a prolonged painful erection.** If this happens to you, go to your nearest hospital at once
- **have yellowing of the skin and whites of your eyes** (jaundice)
- **develop 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 breathing.

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

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

- lack of emotion, feeling excited, agitated or confused
- fits
- blood problems. You may notice signs such as high temperature or chills, sore throat, ulcers in your mouth or throat, unusual tiredness, unexplained bleeding or bruising
- heart changes including fast heart beats, unusual heart beats, heart attack causing chest pain or 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
- higher or lower body temperature than usual
- low blood pressure. You may feel dizzy when standing up. This may affect the elderly more
- 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
- eye changes, such as problems with your eyesight or change in eye colour
- high levels of glucose in the blood (hyperglycaemia). The symptoms of this are feeling thirsty, urinating more often and tiredness.

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

- difficulty sleeping (insomnia)
- drowsiness, dizziness, headache
- changes in your level of alertness
- dry mouth, blocked nose
- feeling sick (nausea), stomach pain
- constipation
- water retention, difficulty passing urine
- fever
- skin rash caused by placing the medicine in contact with your skin, skin rashes, skin reaction to direct sunlight, change in skin colour
- swelling of the breasts (particularly in men) and breast milk production
- light periods or absence of periods
- decrease in sexual performance
- weight gain, loss of appetite
- high cholesterol levels.

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.

5. HOW TO STORE TRIFLUOPERAZINE

Keep out of the reach and sight of children.

Do not store above 25°C. Store in the original container and keep the container tightly closed.

Do not use the tablets after the expiry date, which is stated on the container. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Trifluoperazine tablets contain

Either 1 mg or 5 mg of the active ingredient, (the ingredient that makes the tablets work), trifluoperazine hydrochloride.

The other ingredients are lactose, maize starch, pregelatinised maize starch, magnesium stearate, shellac, talc, titanium dioxide (E171), sucrose, povidone, beeswax, carnauba wax and opalux AS-F-5922 green (trade name containing indigo carmine (E132), quinoline yellow (E104), titanium dioxide (E171), sodium benzoate (E211) and sucrose).

What Trifluoperazine tablets look like and contents of the pack

Trifluoperazine 1 mg and 5 mg tablets are round dark green sugar-coated tablets.

The tablets come in containers of 28, 30, 50, 56, 60, 84, 100, 112, 250, 500 and 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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For more information about this product, please contact the Marketing Authorisation Holder.

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