

Stelazine® 5 mg Tablets

(trifluoperazine hydrochloride)

3302
06.05.21[3]

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.

The product is known by the name above but will be referred to as Stelazine Tablets throughout the rest of this leaflet. This medicine is also available as 1 mg tablets.

What is in this leaflet:

1. What Stelazine Tablets are and what they are used for
2. What you need to know before you take Stelazine Tablets
3. How to take Stelazine Tablets
4. Possible side effects
5. How to store Stelazine Tablets
6. Contents of the pack and other information

1. WHAT STELAZINE TABLETS ARE AND WHAT THEY ARE USED FOR

Stelazine Tablets contain the active ingredient trifluoperazine hydrochloride, which belongs to a class of drugs called phenothiazine tranquilisers. It influences the activity of certain brain cells by decreasing the effect of dopamine, a natural chemical in the brain.

- At a low dose, Stelazine Tablets are used to manage anxiety and depression. It is used in this way for short periods of time
- Stelazine tablets may also be used to treat nausea (feeling sick) and vomiting (being sick)
- At high doses, Stelazine Tablets are used to treat and prevent relapses of schizophrenia (a serious mental illness) and related conditions.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE STELAZINE TABLETS

Do not take Stelazine Tablets:

- 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 disorders, 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 Stelazine (known as phenothiazines) because they have affected your blood cells or caused jaundice (yellowing of the skin and eyes). Ask your doctor about this.
- if 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)
- if you suffer from any abnormality of the cells of blood or are taking medicines which can reduce blood cells.

Warnings and precautions

Talk to your doctor or pharmacist before taking Stelazine Tablets:

- if you or any member of your family is suffering from any disease involving the heart and blood vessels (cardiovascular disease) including chest pain (angina) and irregular heart beats
- if you are suffering from a brain disorder causing tremors, rigidity and slowing of movement (Parkinson's disease)
- if you are suffering from fits (epilepsy)
- if you are suffering from an eye disease called narrow angle glaucoma which causes increased pressure inside the eye, abnormal muscle weakness (Myasthenia gravis) or enlargement of prostate gland
- if you are exposed to extremes in temperature as this medicine can affect body temperature control
- if you are an elderly person
- if you are 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 previously suffered from neuroleptic malignant syndrome (high fever, sweating, unstable blood pressure, muscle rigidity, dazed, drowsy state)
- if 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).

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 Stelazine Tablets

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. The effects of these medicines may change, especially if you are taking:

- sleeping tablets.
- anaesthetics used prior to surgery.
- 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).

Stelazine Tablets with food, drink and alcohol

You should not drink alcohol whilst you are taking this medicine.

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.

It is particularly important not to take Stelazine Tablets during the first three months of pregnancy.

The following symptoms may occur in newborn babies, of mothers that have used Stelazine 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

Stelazine Tablets 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.

Stelazine Tablets contains sucrose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE STELAZINE TABLETS

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

Swallow the tablets with a glass of water. The tablets can be taken with or without food.

Your doctor will decide on a suitable dose depending on your condition.

The recommended dose is:

Adults:

- The normal adult dose for anxiety or vomiting is 2-6mg daily, and for schizophrenia is 10-15mg daily. The dose may be split over two or three times a day.

Children:

- For children aged 6-12 years the dose **for anxiety or nausea and vomiting** is no more than 4mg a day, and for children aged under 12 years the starting dose for **schizophrenia** is no more than 5mg a day. The pharmacist's label on your pack will tell you how much and how often you should take your tablets.

Please read the label carefully. Do not take more than your doctor has recommended.

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 are also taking other medicines.

If you take more Stelazine Tablets than you should:

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

If you forget to take Stelazine Tablets:

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 Stelazine Tablets:

- Continue to take Stelazine Tablets 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 tablets 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.

Stop taking Stelazine Tablets immediately and call your doctor if you experience signs of allergic reaction.

- Signs of an allergic reaction including a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- 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.

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.
- Medicines such as Stelazine Tablets 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).
- 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.

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, skin colouring (pigmentation) and 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

- Stelazine Tablets 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.
- If you have chest pain (angina) and your pain is getting worse.
- 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, blurred vision or eye problems, 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 Stelazine 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. Website:

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 STELAZINE TABLETS**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 box after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original package in order to protect from light and moisture.

Do not throw away medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

If your tablets show any signs of deterioration or discolouration, you should seek the advice of your pharmacist who will tell you what to do.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What Stelazine Tablets contain**

- The active substance is trifluoperazine hydrochloride.
- Each film-coated tablet contains 5 mg trifluoperazine (as hydrochloride).
- The other excipients are: calcium sulfate dihydrate, sucrose, stearic acid, gelatin, maize starch, talc, Opadry OY-4492 blue (hypromellose, titanium dioxide E171, macrogol 400, indigo carmine aluminium lake E132), carnauba wax and purified water.

What Stelazine Tablets look like and contents of the pack

The tablets are blue, round, biconvex, film coated and unmarked on both sides.

They are available in blister packs of 20,30 and 100 tablets.

MANUFACTURER AND PRODUCT LICENCE HOLDER

Manufactured by
VIANEX SA, Factory B, Pallini Attica, Greece.

Procured from within the EU by Product Licence holder:

Star Pharmaceuticals Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD. Repackaged by Servipharm Ltd.

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Blind or partially sighted?

Is this leaflet hard to see or read?

Call 020 8423 2111 to obtain the leaflet in a format suitable for you.

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1. WHAT TRIFLUOPERAZINE TABLETS ARE AND WHAT THEY ARE USED FOR

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- if you are exposed to extremes in temperature as this medicine can affect body temperature control
- if you are an elderly person
- if you are 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
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