

PATIENT INFORMATION LEAFLET
Stelazine® 1 mg Film-Coated Tablets
Stelazine® 5 mg Film-Coated Tablets
trifluoperazine

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 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.

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.
- You should not be given this medicine if you are in a coma, especially if you have taken other central nervous system depressants

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 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).
- if you are an elderly person

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.

Also inform your doctor if you have a family history of abnormal heart beats, unexplained fainting or seizures (e.g. QT prolongation).

- if you suffer 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)
- if you are suffering from any form of dyskinesia (jerky or slow twisting movements of the face or body). see section 4.

- 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).

Dyskinesia:

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.

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, have recently taken or might take 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 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 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.

Ask your doctor or pharmacist for advice before taking any medicine.

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 or pharmacist 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.

Do not take a double dose to make up for a forgotten tablet.

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.

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

4. POSSIBLE SIDE EFFECTS

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

Tell your doctor immediately if you notice any of the following:

- Neuroleptic Malignant Syndrome. This causes a high temperature, rigid muscles, drowsiness, occasional loss of consciousness, and requires emergency admission to hospital for treatment
- Suffer from any form of dyskinesia (jerky or slow twisting movements of the face or body). 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).
- 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.
- Serious abnormal irregular heart beat or abnormal ECG tracings.

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

Other side effects are:

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

- Very rarely, patients may also experience a fast heartbeat, constipation, difficulty or inability to pass urine or a high temperature
- There have been very rare reports of jaundice (yellowing of skin and whites of eyes), eye problems and skin colouring (pigmentation)
- 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 have complained of feeling slowed down, whilst others of being agitated.
- 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, weight gain, water retention causing swelling or confusion. These are dependent on the dose that you are taking and tend to disappear when you have finished taking the medicine.

Your doctor should check your progress regularly to make sure no unwanted effects are developing. 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 HPRA Pharmacovigilance

Website: www.hpra.ie

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 carton and blister 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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Stelazine Tablets contains

- The active substance is trifluoperazine hydrochloride. Each film-coated tablet contains 1 mg or 5 mg of trifluoperazine (as hydrochloride).
- The other ingredients are as follows,
Tablet core: calcium sulfate dihydrate, sucrose, maize starch, gelatin, talc and stearic acid.
Film-coating: hypromellose (E464), titanium dioxide (E171), macrogol 400, indigo carmine (E132) and carnauba wax.

What Stelazine Tablets look like and contents of the pack

Stelazine 1 mg Film-coated Tablets are blue aqueous coated tablets having 'FW231' embossed on one face. Stelazine 5 mg Film-coated Tablets are blue aqueous coated tablets having 'FW241' embossed on one face. They are packed in opaque PVC/aluminium foil blisters in packs containing 28, 56, 100 and 112 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Amdipharm Limited,
Temple Chambers, 3 Burlington Road,
Dublin 4, Ireland

Manufacturer:

Mercury Pharmaceuticals Ltd.,
Capital House, 85 King William Street,
London EC4N 7BL, UK

Alternate manufacturer:

Bristol Laboratories Ltd.,
Laporte Way, Luton Bedfordshire, LU4 8WL, UK.

Or

Famar Health Care Services,
Avda. Leganés. 62, Alcorcón, Madrid, 28923, Spain

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PA1142/037/001, PA1142/037/002

This leaflet was last revised in July 2020.