

Stelazine®

Film-coated tablets 1 mg, 2 mg and 5 mg

Trifluoperazine hydrochloride

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking Stelazine.

This leaflet answers some common questions about Stelazine. It does not contain all the available information.

Reading this leaflet does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Stelazine against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may want to read it again.

What Stelazine is used for

Stelazine contains trifluoperazine hydrochloride as the active ingredient. It belongs to a group of medicines called phenothiazine neuroleptics. It helps to correct chemical imbalances in the brain, which may cause mental illness. These chemicals may also affect the parts of the brain which control nausea and vomiting. Stelazine is used to treat mental illnesses with disturbances in thinking, feelings and behaviour. It may also be used to treat nausea and vomiting, or used short term in patients with severe anxiety, tension and agitation.

Your doctor may have prescribed this medicine for another reason.

Ask your doctor if you have questions about why it has been prescribed for you.

Stelazine is available only with a doctor's prescription.

Stelazine is not addictive.

Before you take Stelazine

Stelazine is not suitable for everyone.

When you must not take it

Stelazine must not be given to anyone who has reduced consciousness due to medication, is unconscious or in a coma.

Do not take Stelazine if you have an allergy to it or to:

- any other medicine containing trifluoperazine
- any of the ingredients listed at the end of this leaflet
- other similar medicines known as 'phenothiazines'.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take Stelazine if you have or have had any of the following medical conditions:

- liver disease
- blood or bone marrow disorder

- pheochromocytoma, a rare tumour of the adrenal gland, which sits near the kidneys

- heart failure

- failed circulation due to extremely low blood pressure.

Do not take it after the expiry date printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking Stelazine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- heart problems, including angina or irregular heart beat
- any condition which increases your risk of having a stroke, such as diabetes, high blood pressure, high cholesterol, blood vessel disease or transient ischaemic attack (TIA or 'mini-stroke')
- any condition which increase your risk of having a blood clot, such as surgery, being bed-ridden, or having cancer
- low blood pressure
- breast cancer
- epilepsy, seizures or fits
- brain injury or disease
- memory impairment which may affect your daily activities
- glaucoma, a condition in which there is usually a build-up of fluid in the eye
- prostate problems
- myasthenia gravis, a condition that results in muscle weakness
- Parkinson's disease
- lung disease (e.g. pneumonia).

Also tell your doctor if you or any member of your family has ever had:

- heart disease
- blood clotting disorder, including heart attack, stroke, DVT or pulmonary embolism
- diagnosis of "QT prolongation" on electrocardiogram (ECG).

Before taking the first dose, tell your doctor or pharmacist if you have taken Stelazine or other similar medicine before and became unwell, in particular with:

- bone marrow or blood disorder
- liver problems or jaundice.

Tell your doctor if you are more than 80 years old.

Tell your doctor if you are pregnant or intend to become pregnant.

Like most medicines of this kind, Stelazine is not recommended to be used during pregnancy unless advised by your doctor. Your doctor will discuss the risks and benefits of using it if you are pregnant, and

advise you regarding the recommended dose and duration of treatment.

Tell your doctor if you are breast-feeding or plan to breast-feed.

It is recommended that you do not breast-feed while taking Stelazine, as it may pass into breast milk and may affect your baby.

Tell your doctor if you will be exposed to extremes of heat or cold.

Stelazine may reduce your ability to adapt to extremes of temperature.

Do not give Stelazine to a child aged 3 years and under, unless instructed to by your doctor.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Stelazine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell any health professional who is prescribing a new medicine for you that you are taking Stelazine.

Some medicines and Stelazine may interfere with each other. These include:

- medicines used to control depression
- medicines used to treat anxiety or to help you sleep
- medicines that are known to cause salt (electrolyte) imbalance in the body
- medicines used to treat high blood pressure or to treat other heart conditions (e.g. propranolol, guanethidine, amiodarone, disopyramide, procainamide)
- anticonvulsants, medicines used to control epilepsy, e.g. phenytoin
- medicines used to treat Parkinson's disease (e.g. levodopa)
- strong pain killers
- actinomycin D, a medicine used to treat cancer
- some medicines used to prevent your blood from clotting
- thiazide diuretics, medicines used to treat fluid build-up in your body
- atropine, a medicine which may be used in some eye drops or cough and cold preparations
- antacids, medicines used to treat heartburn
- lithium, used to treat manic episodes in bipolar disorder
- desferrioxamine, used to treatment of acute iron toxicity.

The above medicines may be affected by Stelazine, or may affect how well it works. You may need different amounts of your medicine, or take it at different times, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Stelazine.

How to take Stelazine

Read the label carefully and follow all directions given to you by your doctor or pharmacist.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

The starting dose of Stelazine for adults is usually 1 mg or 2 mg twice a day. The starting dose for children can vary, so consult your doctor. If necessary, your doctor may increase or decrease the dose you take each day.

Your doctor will tell you how much you should take. The dose will vary according to your illness.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take. This depends on your condition and whether or not you are taking any other medicines.

If you take the wrong dose, Stelazine may not work as well and your problem may not improve.

Swallow Stelazine tablets with a glass of water.

When to take it

Stelazine tablets are usually taken once or twice daily.

Take it at about the same times each day.

Taking it at the same times each day will have the best effect. It will also help you to remember when to take it.

How long to take it

Continue taking the medicine for as long as your doctor tells you to.

Stelazine helps to control your condition, but it does not cure it. Therefore, you must take it every day. It is important to keep taking the medicine even if you feel well.

If you are unsure whether you should stop taking Stelazine, talk to your doctor or pharmacist.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Do not try to make up for missed doses by taking more than one dose at a time.

This may increase the chance of getting an unwanted side effect.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for hints.

While you are taking Stelazine

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Stelazine. Likewise, tell any other doctors, dentists and pharmacists who are treating you that you are taking this medicine.

If you are going to have surgery, tell the surgeon, anaesthetist or dentist that you are taking Stelazine.

Stelazine may affect other medicines used during surgery and you may need additional monitoring.

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor immediately if you, or a person you're caring for, has any thoughts of suicide or self-harm while taking Stelazine.

All mentions of suicide or violence must be taken seriously.

Patients and care givers should pay attention to any of the following warning signs of suicide-related behaviour. Tell your doctor immediately, or go to the nearest hospital for treatment if you notice:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation.

If you need to have any medical tests while you are taking Stelazine, tell your doctor.

Stelazine may affect the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may want to do blood tests or check your eyes, heart, liver and kidneys from time to time. This helps to prevent unwanted side effects.

See your doctor if you feel that your condition is not improving or is getting worse.

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.

This medicine is only intended for the person it has been prescribed for.

Do not take Stelazine to treat any other complaints unless your doctor tells you to.

Do not stop taking Stelazine without checking with your doctor, even if you are feeling better.

If you stop taking Stelazine suddenly, your condition may worsen or your chance of getting an unwanted side effect may increase. To prevent this, your doctor may gradually reduce the amount of Stelazine you take each day before stopping the medicine completely.

Do not take any medicines that cause drowsiness while you are taking Stelazine, unless recommended by your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Stelazine affects you.

As with other phenothiazine medicines, Stelazine may cause sleepiness, poor co-ordination, dizziness or affect vision in some people. Make sure you know how you react to it before you drive a car, operate machinery, or do anything else that could be dangerous if you feel dizzy or light-headed or if your sight is affected. If this occurs do not drive. If you drink alcohol, sleepiness or poor co-ordination may be worse.

If Stelazine makes you feel light-headed, dizzy or faint, get up slowly when getting up from a sitting or lying position.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Be careful when drinking alcohol while taking Stelazine.

Combining Stelazine and alcohol can make you more sleepy, dizzy or light-headed. Your doctor may suggest to avoid alcohol while you are being treated with Stelazine.

Protect your skin when you are in the sun, especially between 10am and 3pm.

If you are outdoors, wear protective clothing and use a 30+ sunscreen.

If your skin appears to be burning, tell your doctor.

Stelazine may cause your skin to be much more sensitive to sunlight than it is normally. This could cause a skin rash, itching, redness, or severe sunburn.

Make sure you keep cool in hot weather and keep warm in cool weather.

Stelazine may affect the way your body reacts to temperature changes.

Avoid direct contact with insecticides.

Stelazine can make the effect of insecticides worse on your body. Wear gloves, face mask and cover up as much as possible when using insecticides.

In case of overdose

If you take too much

Immediately telephone your doctor, or the Poisons Information Centre (Australia telephone 13 11 26 or New Zealand – telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Stelazine.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Stelazine, you may feel sleepy, dizzy or agitated. You may also have a dry mouth, fit or seizure, or muscle spasms.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Stelazine.

Like all medicines, Stelazine may occasionally cause side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- drowsiness, fatigue, weakness
- dizziness
- restlessness
- sleeplessness
- dullness

- headache
- blurred vision or difficulty focussing
- nausea
- constipation
- increased or decreased appetite, weight changes
- dry mouth
- blocked nose
- impaired sexual function in men
- painful, swollen breasts, or breast enlargement in men
- unusual secretion of breast milk
- changes in your menstrual periods
- swelling of your hands, feet and ankles.

These side effects are usually mild and transient at lower doses.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- persistent painful erection
- rash, itching or flaking, peeling skin
- symptoms of sunburn (such as redness, itching, swelling or blistering of the skin) which occurs more quickly than normal
- yellowing of the skin and/or eyes
- changes in colour vision or difficulty in seeing at night
- fever
- tiredness, headaches, being short of breath when exercising, dizziness and looking pale
- bleeding or bruising more easily than normal
- difficulty passing urine
- fast or irregular heart beat
- red or painful eye
- agitation, confusion or nervousness
- mask-like face, drooling, shaking, rigid muscles, walking stiffly
- 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.

These may be serious side effects. You may need urgent medical attention.

If any of the following happen, stop taking Stelazine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- serious allergic reaction (swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing)
- sudden onset of uncontrollable muscle spasms affecting the eyes, head, neck and body
- sudden onset of pain in the legs, chest pain or difficulty in breathing
- uncontrollable twitching or jerking movements of the arms and legs
- sudden increase in body temperature, sweating, fast heart beat, muscle stiffness, difficulty breathing (which may lead to reduced awareness or unconsciousness).

These are very serious side effects; you may need urgent medical attention or hospitalisation.

Stop taking Stelazine and tell your doctor immediately if you notice any uncontrolled movements of the tongue, face, mouth or jaw, such as puffing of the cheeks, puckering of the mouth or chewing movements.

These are symptoms of a very rare condition called tardive dyskinesia, which may develop in people taking phenothiazine medicines, including Stelazine. This condition is more likely to occur during long term treatment with Stelazine, especially in elderly women. In very rare cases, this may be permanent. However, if detected early, these symptoms are usually reversible.

You may notice some side effects after you have finished taking Stelazine.

Some side effects can only be found if your doctor does tests on your blood or urine.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

After taking Stelazine

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep Stelazine in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window sill. Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it and any other medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not keep Stelazine past its expiry date.

Disposal

If your doctor tells you to stop taking Stelazine, or the tablets have passed their expiry date (as shown on the labelling), return any unused medicine to your pharmacy.

Product description

What it looks like

Stelazine is available in blister packs of 100 tablets.

- Stelazine 1 mg tablets are 6.5 mm blue round tablets containing 1 mg trifluoperazine.
- Stelazine 2 mg tablets are 7.3 mm blue round tablets containing 2 mg trifluoperazine.
- Stelazine 5 mg tablets are 8.1 mm blue round tablets containing 5 mg trifluoperazine.

Ingredients

Active ingredient:

- trifluoperazine hydrochloride

Inactive ingredients:

- calcium sulfate
- sucrose
- maize starch
- gelatin
- purified talc

- stearic acid
- purified water
- Opadry OY-S-4492.

Stelazine does not contain lactose, gluten, or tartrazine.

Sponsor details

Distributed in Australia by:

Amdipharm Mercury (Australia) Pty Ltd
Level 1, 134 Willoughby Road
Crows Nest NSW 2065

Stelazine 1 mg tablets blister pack: AUST R 66873

Stelazine 2 mg tablets blister pack: AUST R 66874

Stelazine 5 mg tablets blister pack: AUST R 66875

Distributed in New Zealand by:

Boucher & Muir (NZ) Ltd t/a Mercury
Pharma (NZ)
39 Anzac Road
Browns Bay
Auckland 0753

Date of preparation

This leaflet was prepared on 31 August 2016.

Amdipharm Mercury (Australia) Pty Ltd is licensed to use the trademark Stelazine.