

# Stelazine® 1mg/5ml Syrup

(trifluoperazine hydrochloride)

## Patient Information Leaflet

**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.

### What is in this leaflet:

- 1) What Stelazine 1mg/5ml Syrup is and what it is used for
- 2) What you need to know before you take Stelazine 1mg/5ml Syrup
- 3) How to take Stelazine 1mg/5ml Syrup
- 4) Possible side effects
- 5) How to store Stelazine 1mg/5ml Syrup
- 6) Contents of the pack and other information

### 1) What Stelazine 1mg/5ml Syrup is and what it is used for

Stelazine 1mg/5ml Syrup contains the active ingredient trifluoperazine hydrochloride, which belongs to a class of drugs called phenothiazine tranquilisers, also referred to as a neuroleptic drug. 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 1mg/5ml Syrup is used to manage anxiety and depression. It is used in this way for short periods of time. Stelazine 1mg/5ml Syrup may also be used to treat nausea (feeling sick) and vomiting (being sick).
- At high doses, Stelazine 1mg/5ml Syrup is used to treat and prevent relapses of schizophrenia (a serious mental illness). It can also be used for short periods of time to treat bad agitation or dangerous behaviour.

### 2) What you need to know before you take Stelazine 1mg/5ml Syrup

#### DO NOT take Stelazine 1mg/5ml Syrup if:

- You know that you are allergic to trifluoperazine hydrochloride or any of the other ingredients of Stelazine 1mg/5ml Syrup (see section 6 of this leaflet).
- You are suffering from liver problems, blood disease, 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 or eyes). Ask your doctor about this.

#### Take special care with Stelazine 1mg/5ml Syrup and tell your doctor if you are:

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Stelazine 1mg/5ml Syrup if you are:

- suffering from any disease involving the heart and blood vessels (cardiovascular disease) including chest pain (angina) and irregular heart beats
- suffering from a brain disorder causing tremors, rigidity and slowing of movement (Parkinson's disease)
- suffering from fits (epilepsy)
- suffering from an eye disease called narrow angle glaucoma which causes increased pressure inside the eye,
- suffering from abnormal muscle weakness (Myasthenia gravis)
- suffering from an enlargement of prostate gland
- exposed to extremes in temperature as this medicine can affect body temperature control
- an elderly person
- 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 have had a stroke or have any of the following that can increase your risk of having a stroke (e.g. heart attack, uncontrolled high blood pressure, diabetes, family history of strokes, you smoke or drink excess alcohol). 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 1mg/5ml Syrup

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,
- 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)

You should tell your doctor or dentist that you are taking Stelazine before being given an anaesthetic.

### Stelazine 1mg/5ml Syrup with food, drink and alcohol

You should not drink alcohol whilst you are taking this medicine. Stelazine 1mg/5ml Syrup can be taken with or without food.

### 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 1mg/5ml Syrup during the first three months of pregnancy. Ask your doctor or pharmacist for advice before taking any medicine. 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

Stelazine 1mg/5ml Syrup 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.

Trifluoperazine 1mg/5ml Syrup contains:

- Sorbitol (E420), which is a sugar. If you have been told by your doctor that you are intolerant to some sugars, contact your doctor before taking this medicine. Sorbitol can also cause stomach upset and diarrhoea in some patients.
- Sunset yellow (E110) which may cause allergic reactions.
- Sodium benzoate which may increase the risk of jaundice in newborn babies.
- This medicinal product contains 55.22 mmol sodium per dose. To be taken into consideration for patients on a controlled sodium diet.

### 3) How to take Stelazine 1mg/5ml Syrup

Always take Stelazine 1mg/5ml Syrup exactly as your doctor or pharmacist has told you. The pharmacist's label on your pack will tell you how much and how often you should take your Syrup. Please read the label carefully. You should check with your doctor or pharmacist if you are not sure. Do not take more than your doctor has recommended. Your doctor will decide on a suitable dose depending on your condition. The usual dose is shown in the table below. You will usually need to take your medicine twice or three times a day, depending on the dose your doctor has chosen for you.

The recommended dose is:

Remember each 5ml spoonful of syrup contains 1mg of "Trifluoperazine"

Patient Type	Low dosage For the treatment of anxiety or nausea and vomiting	High dosage For the control of schizophrenia and related conditions
Adults	The usual dose is 2 mg to 6mg a day	High dose in adults is 5-25mg a day in divided doses

Elderly (over 65 years of age)	The starting dose of syrup should be no more than half that of adult patients	The starting dose of syrup should be no more than half that of adult patients
Children	For children aged 3-5 years, the dose is no more than 1mg a day. For children aged 6-12 years the dose is no more than 4mg a day.	High dose in children (aged 6-12 years) is 5mg in divided doses.

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 taking this medicine for a long time or are also taking other medicines.

#### **If you take more Stelazine 1mg/5ml Syrup than you should:**

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

If you forget to take your Stelazine 1mg/5ml Syrup:

#### **If you forget to take Stelazine 1mg/5ml Syrup**

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 1mg/5ml Syrup**

Continue to take Stelazine 1mg/5ml Syrup 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 Syrup 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, Stelazine 1mg/5ml Syrup can sometimes cause side effects, although not everybody gets them. If you notice any of these symptoms seek medical advice immediately. 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.

A life-threatening irregular heart beat called torsades de pointes; heart stopping (cardiac arrest) and unexplained death.

#### **Other side effects are:**

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

#### **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 1mg/5ml Syrup 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).

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

- Patients may experience a fast 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.

#### **Not known: frequency cannot be estimated from the available data**

- If you have chest pain (angina) and your pain is getting worse.
- Stelazine 1mg/5ml Syrup 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 other of being agitated.
  - 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.
  - 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, 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.

Your doctor should check your progress regularly if you are on Stelazine 1mg/5ml Syrup 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://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 1mg/5ml Syrup**

- **Keep out of the sight and reach of children.**
- Do not use Stelazine 1mg/5ml Syrup after the expiry date which is stated on the box. The expiry date refers to the last day of that month. If your Syrup is out of date, take it to your pharmacist who will get rid of it safely.
- Do not store above 25°C. Store in the original container to protect from light.
- If the medicine become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- 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 protect the environment.

#### **6) Contents of the pack and other information**

##### **What Stelazine 1mg/5ml Syrup contain**

The active substance in Stelazine 1mg/5ml Syrup is trifluoperazine hydrochloride. Each 5ml syrup contains 1mg of trifluoperazine present as hydrochloride.

Stelazine 1mg/5ml Syrup also contains sodium saccharin (E954), sodium benzoate (E211), anhydrous citric acid (E330), sodium citrate (E331), sorbitol liquid (non-crystallising) (E420), quinoline yellow (E104), sunset yellow (E110), peach flavour and purified water.

##### **What Stelazine 1mg/5ml Syrup looks like and contents of the pack**

Stelazine 1mg/5ml Syrup is a clear pale yellow, peach flavoured syrup and comes in amber glass bottles, containing 200ml syrup.

PL 46420/0407 Stelazine 1mg/5ml Syrup **POM**

##### **Who makes and repackages your medicine?**

Your medicine is manufactured by Laleham Health and Beauty Limited, Fairfield, Bradshaw Lane, Greenhalgh, Kirkham, Preston, Lancashire, PR4 3JA, UK. Procured from within the EU and repackaged by the Product Licence holder: Suerte Pharma Ltd., 4/5 Northolt Trading Estate, Northolt, Middlesex, UB5 5QS.

Leaflet date: 22.07.2020

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leaflet in a format suitable for you.**

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### 1) What Trifluoperazine 1mg/5ml Syrup is and what it is used for

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- suffering from an enlargement of prostate gland
- exposed to extremes in temperature as this medicine can affect body temperature control
- an elderly person
- if you suffer from loss of cognitive (memory, language, intelligence) ability - dementia.
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- drugs causing electrolyte imbalances (e.g. diuretics)

You should tell your doctor or dentist that you are taking Trifluoperazine before being given an anaesthetic.

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You should not drink alcohol whilst you are taking this medicine. Trifluoperazine 1mg/5ml Syrup can be taken with or without food.

### Pregnancy and breast feeding

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Patient Type	Low dosage For the treatment of anxiety or nausea and vomiting	High dosage For the control of schizophrenia and related conditions
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Children	For children aged 3-5 years, the dose is no more than 1mg a day. For children aged 6-12 years the dose is no more than 4mg a day.	High dose in children (aged 6-12 years) is 5mg in divided doses.

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 taking this medicine for a long time or are also taking other medicines.

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Like all medicines, Trifluoperazine 1mg/5ml Syrup can sometimes cause side effects, although not everybody gets them. If you notice any of these symptoms seek medical advice immediately. 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.

A life-threatening irregular heart beat called torsades de pointes; heart stopping (cardiac arrest) and unexplained death.

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#### **Rare: may affect up to 1 in 1,000 people**

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- Patients may experience a fast 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.

#### **Not known: frequency cannot be estimated from the available data**

- If you have chest pain (angina) and your pain is getting worse.
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The active substance in Trifluoperazine 1mg/5ml Syrup is trifluoperazine hydrochloride. Each 5ml syrup contains 1mg of trifluoperazine present as hydrochloride.

Trifluoperazine 1mg/5ml Syrup also contains sodium saccharin (E954), sodium benzoate (E211), anhydrous citric acid (E330), sodium citrate (E331), sorbitol liquid (non-crystallising) (E420), quinoline yellow (E104), sunset yellow (E110), peach flavour and purified water.

##### **What Trifluoperazine 1mg/5ml Syrup looks like and contents of the pack**

Trifluoperazine 1mg/5ml Syrup is a clear pale yellow, peach flavoured syrup and comes in amber glass bottles, containing 200ml syrup.

PL 46420/0407 Trifluoperazine 1mg/5ml Syrup

**POM**

##### **Who makes and repackages your medicine?**

Your medicine is manufactured by Laleham Health and Beauty Limited, Fairfield, Bradshaw Lane, Greenhalgh, Kirkham, Preston, Lancashire, PR4 3JA, UK. Procured from within the EU and repackaged by the Product Licence Holder: Suerte Pharma Ltd., 4/5 Northolt Trading Estate, Northolt, Middlesex, UB5 5QS.

**Leaflet date: 22.07.2020**

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