

- Swelling, discolouration or pain in your leg, arm or in your chest, or breathing problems, which may be caused by a blood clot.
- 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.

If you stop taking this medicine regularly, you may suddenly feel sick, be sick, sweat and have difficulty in sleeping. Do not stop taking this medicine without the advice of your doctor.

Some patients may 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. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie. E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

### 5. HOW TO STORE STELAZINE SYRUP

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 label after "Exp". The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### Shelf Life

Diluted Syrup: 4weeks. Discard any unused diluted syrup.

### 6. CONTENTS OF THE PACK AND OTHER INFORMATION

#### What Stelazine Syrup contains

The active substance in Stelazine Syrup is trifluoperazine.

Each 5ml spoonful of Stelazine Syrup contains 1mg trifluoperazine.

Stelazine Syrup also contains sodium saccharin, sodium benzoate (E211), anhydrous citric acid (E330), sodium citrate, sorbitol (E420), quinoline yellow (E104), sunset yellow (E110), peach flavour and purified water.

#### What Stelazine Syrup looks like and contents of the pack

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

#### Marketing Authorisation Holder

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

#### Manufacturer

Laleham Health and Beauty Limited,  
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This leaflet was last revised in December 2018.

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LF-118210-01  
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### PATIENT INFORMATION LEAFLET

## Stelazine® 1mg/5ml Syrup

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. Do not pass it on to others. It may harm, 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.

#### What is in this leaflet

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

### 1. WHAT STELAZINE SYRUP IS AND WHAT IT IS USED FOR

Stelazine Syrup contains the active ingredient trifluoroperazine hydrochloride, which belongs to a class of drugs called phenothiazine tranquillisers, 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.

It is used to manage anxiety, hallucinations and delusions. It can also be used to treat nausea (feeling sick) and vomiting (being sick).

### 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE STELAZINE SYRUP

DO NOT take Stelazine Syrup if:

- You know that you are allergic to trifluoroperazine hydrochloride or any of the other ingredients of this medicine (listed in section 6 of this leaflet).
- You are suffering from liver problems, blood disease, or 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). Ask your doctor about this
- Do not take Stelazine Syrup if you are pregnant, think you may be pregnant or are planning to become pregnant, or while breast feeding, unless your doctor decides that treatment is essential. It is particularly important not to take Stelazine Syrup during the first three months of pregnancy.

Stelazine treatment is to be discontinued if you

- suffer from any form of dyskinesia (jerky or slow twisting movements of the face or body). see section 4
- suffer from Neuroleptic Malignant syndrome (fever, muscular rigidity, altered mental status, and autonomic dysfunction). see section 4

You should not be given this medicine if you are in a coma.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you are:

- suffering from any disease involving the heart and blood vessels (cardiovascular disease) including chest pain (angina) and irregular heartbeats, or have an increased risk of having a stroke (your doctor can advise you)
- 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
- suffering from blood clots or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.
- exposed to extremes in temperature as this medicine can affect body temperature control
- 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).

When you stop taking Stelazine Syrup, the doctor will lower your dose gradually. If you stop taking the medicine suddenly you may get withdrawal symptoms. Signs could include feeling sick, sweating, difficulty in sleeping and movements that you can't control. see section 3 and 4

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

Tell your doctor or pharmacist if you are taking, have recently taken or might take, any other medicines. 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 which alter the way that your heart beats (by prolonging the Q-T interval) (e.g. clarithromycin, sunitinib, prochlorperazine)
- medicines which cause changes to the amount of sodium, calcium and potassium (electrolytes) in your blood (e.g. hydrocortisone, birth control pills, and antibiotics and antifungals such as amphotericin B and trimethoprim).

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

**Stelazine Syrup with alcohol**

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

**Pregnancy, breast feeding and fertility**

Do not take Stelazine Syrup if you are pregnant, think you may be pregnant or are planning to become pregnant, or while breast feeding, unless your doctor decides that treatment is essential. It is particularly important not to take Stelazine Syrup 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.

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

**Driving and using machines**

This medicine 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 Syrup also contains:**

- sorbitol (E420), which is a sugar which may have a mild laxative effect. Calorific value 2.6 Kcal/g sorbitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- sunset yellow (E110) which may cause allergic reactions.

**3. HOW TO TAKE STELAZINE SYRUP**

Always take this medicine exactly as your doctor 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. 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.

Remember that each 5ml spoonful of syrup contains 1mg of trifluoroperazine hydrochloride, the active ingredient in this medicine.

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

Low dosage: is used for short-term management of anxiety states, depressive symptoms secondary to anxiety, and agitation. It can also be used to treat nausea (feeling sick) and vomiting (being sick).

High dosage: is used for hallucinations, delusions and severe agitation.

Patient Type	Low dosage	High dosage
Adults	The usual dose is 2 mg to 6mg a day in divided doses.	The usual dose is 5 mg to 25 mg a day in divided doses.
Elderly (over 65 years of age)	Elderly patient's dose should be reduced by at least half of the adult dose.	Elderly patient's dose should be reduced by at least half of the adult dose.
Children : Aged 6 to 12 years:	For children aged 6-12 the usual dose is 1 mg to 4 mg a day in divided doses.	High dose in children (aged 6-12 years) is 5mg in divided doses.

**If you take more Stelazine 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**

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 Syrup**

Continue to take Stelazine 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 hallucinations and delusions, 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.

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

- Medicines such as Stelazine 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). 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.
- Rarely 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.
- Rarely, patients may experience a fast or irregular heartbeat, and very rarely may experience constipation, difficulty or inability to pass urine or a high temperature.
- This medicine 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.
- If you have chest pain (angina) and your pain is getting worse
- Very rarely, jaundice (yellowing of skin and whites of eyes), eye problems, skin colouring (pigmentation) and blood problems.
- 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.