Stelazine® 1mg/5ml Syrup
(trifluoperazine hydrochloride)

Patient Information Leaflet

Read all of this leaflet carefully before you start taking this medicine.

• Keep this leaflet. You may need to read it again.
• If you have any further questions, ask your doctor or pharmacist.

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 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.

• 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) 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:

• 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, and

• 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.

Taking other medicines

Please 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.

Taking Stelazine 1mg/5ml Syrup with food and drink

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

Do not take Stelazine 1mg/5ml 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 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.

Important information about some of the ingredients of Stelazine 1mg/5ml Syrup

This medicine also 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.

Sodium benzoate (E211), which is an anti-bacterial used to prevent mould growth. It may cause allergic reactions. Do not take this medicine if you are allergic to sodium benzoate.

Sodium benzoate 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 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.

Remember each 5ml spoonful of syrup contains 1mg of “Trifluoperazine”
Tell your doctor immediately if you notice any of the following:

- 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). 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) Further information

**What Stelazine 1mg/5ml Syrup contain**
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 10383/2119 Stelazine 1mg/5ml Syrup POM

**Who makes and repackages your medicine?**
Your medicine is manufactured by Universal Products (Lytham) Manufacturing Ltd., Fairfield, Bradshaw Lane, Greenhalgh, Preston, Lancashire, PR4 3JA. Procured from within the EU and repackage by the Product Licence Holder: Primecrown Ltd., 4/5 Northolt Trading Estate, Northolt, Middlesex, UB5 5QS.

**Leaflet date:** 22.08.2014
Trifluoperazine 1mg/5ml Syrup
(trifluoperazine hydrochloride)

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- 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 them, even if their symptoms are the same as yours.
- 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.

In this leaflet:
1) What Trifluoperazine 1mg/5ml Syrup is and what it is used for
Trifluoperazine 1mg/5ml Syrup contains the active ingredient trifluoperazine hydrochloride, which belongs to a class of drugs called phenothiazine tranquillizers, 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.

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2) Before you take Trifluoperazine 1mg/5ml Syrup
DO NOT take Trifluoperazine 1mg/5ml Syrup if:
- You know that you are allergic to trifluoperazine hydrochloride or any of the other ingredients of Trifluoperazine 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 Trifluoperazine (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 Trifluoperazine 1mg/5ml Syrup and tell your doctor 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, uncompromised blood pressure, diabetes, family history of strokes, you smoke or drink excess alcohol).

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Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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- anticholinergic medicines used to reduce saliva and lung secretions (e.g. atropine, procyclidine)
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- medicines used to treat iron poisoning (desferrioxamine)
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- medicines for psychiatric conditions (neuroleptics)
- heart medicines which prolong the QT interval (e.g quinidine, disopyramide, procainamide, amiodarone, sotalol)
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You should tell your doctor or dentist that you are taking Trifluoperazine before being given an anaesthetic.

Taking Trifluoperazine 1mg/5ml Syrup with food and drink
You should not drink alcohol whilst you are taking this medicine.

Trifluoperazine 1mg/5ml Syrup can be taken with or without food.

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Trifluoperazine 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.

Important information about some of the ingredients of Trifluoperazine 1mg/5ml Syrup
This medicine also 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 Trifluoperazine 1mg/5ml Syrup
Always take Trifluoperazine 1mg/5ml Syrup 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. 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.

Remember each 5ml spoonful of syrup contains 1mg of “Trifluoperazine”
Tell your doctor immediately if you notice any of the following:

Like all medicines, these symptoms seek medical advice immediately.

- difficulty in breathing. If you notice any of these symptoms suddenly, your symptoms may come back.
- Blood clots in the veins especially in the legs (spleen, lungs)

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.

4) Possible side-effects

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.

Like all medicines, Trifluoperazine 1mg/5ml Syrup can sometimes cause side effects, although not everybody gets them.

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

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

During your treatment you 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.

If you stop taking Trifluoperazine 1mg/5ml Syrup

Continue to take Trifluoperazine 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.

If you take more Trifluoperazine 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 Trifluoperazine 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.

5) How to store Trifluoperazine 1mg/5ml Syrup

- Keep out of the sight and reach of children.
- Do not use Trifluoperazine 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) Further information

What Trifluoperazine 1mg/5ml Syrup contain

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.

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