

Slow-Trasicor 160 mg Tablets

Oxprenolol hydrochloride



Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Please 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 symptoms 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. See section 4.

What is in this leaflet:

1. What Slow-Trasicor Tablets are and what they are used for
2. What you need to know before you take Slow-Trasicor Tablets
3. How to take Slow-Trasicor Tablets
4. Possible side effects
5. How to store Slow-Trasicor Tablets
6. Contents of the pack and other information

1. What Slow-Trasicor Tablets are and what they are used for

The name of your medicine is Slow-Trasicor 160 mg Tablets (called Slow-Trasicor Tablets in this leaflet).

Slow-Trasicor Tablets contain oxprenolol hydrochloride. Oxprenolol hydrochloride belongs to a group of medicines called beta-blockers.

Slow-Trasicor Tablets are used in adults to treat high blood pressure and to reduce or prevent chest pain (angina).

2. What you need to know before you take Slow-Trasicor Tablets Do not take Slow-Trasicor Tablets if you:

- are allergic to oxprenolol, any other beta-blockers, or any of the other ingredients of Slow-Trasicor Tablets listed in section 6 (allergic reactions include mild symptoms such as itching and/or rash. More severe symptoms include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing);
- have a history of asthma or wheezing attacks;
- suffer from chronic obstructive pulmonary disease (symptoms include shortness of breath, cough);
- have any heart problems (e.g. heart failure, cardiogenic shock, heart block [second or third degree atrioventricular block], history of cor pulmonale);
- have an untreated tumour of the adrenal gland (phaeochromocytoma);
- are suffering from severe peripheral circulatory problems;
- have any heart rhythm disorders (sick-sinus syndrome);
- have a very low pulse rate (less than 50 beats per minute);
- suffer from low blood pressure;
- have Prinzmetal's angina (a specific type of chest pain);
- have high levels of acid in your blood (metabolic acidosis);
- have severe kidney problems;
- have not been eating (fasting) for a long period of time;
- are planning any procedures which involve an anaesthetic;
- are receiving an injection of a medicine called verapamil.

Slow-Trasicor Tablets are not recommended for use in children.

Warnings and precautions

Talk to your doctor or pharmacist before taking Slow-Trasicor Tablets if you:

- have a first degree atrioventricular block (a heart problem where electrical signals to your heart are slowed down);
- have heart disease or a weak heart;
- have recently suffered a heart attack;
- suffer from serious blood vessel disorders (arteriosclerosis);
- suffer with muscle weakness (myasthenia gravis);
- have a skin condition called psoriasis;

- are diabetic and are taking insulin or any other anti-diabetic drugs;
- have low blood sugar levels;
- have ever had a serious allergic reaction (e.g. abnormal sensitivity to insect bites or stings, severe eczema or hayfever);
- have an overactive thyroid gland (hyperthyroidism);
- have any serious liver or kidney problems;
- have Raynaud's disease (poor circulation in the hands and feet) or other problems with your circulation.

If you are going to have a general anaesthetic, you should tell the doctor or dentist in charge that you are taking Slow-Trasicor Tablets, as your treatment might need to be stopped a few days before the surgery.

Slow-Trasicor Tablets may interfere with some tests performed by your doctor when measuring levels of a steroid called cortisol in your urine.

If any of these apply to you, or if you are not sure, tell your doctor before being treated with Slow-Trasicor Tablets.

Other medicines and Slow-Trasicor Tablets

Tell your doctor of pharmacist if you are taking, or have recently taken, or might take any other medicines, including medicines obtained without prescription.

This is especially important if you are taking:

- any calcium channel blockers (used to treat high blood pressure and angina) (e.g. verapamil, nifedipine, diltiazem);
- any barbiturates (e.g. phenobarbitone);
- any other medicines for high blood pressure (hypertension);
- a medicine which belongs to a group of medicines called sympathomimetics (e.g. phenylephrine, theophylline).

or if you are taking any medicines for:

- problems such as depression or mental illness (lithium, monoamine oxidase inhibitors (MAOIs), tri-cyclic antidepressants, phenothiazides);
- heart failure (e.g. digoxin);
- an irregular heart beat (e.g. lidocaine, amiodarone, disopyramide);
- diabetes (e.g. insulin or other sugar lowering anti-diabetic medicines);
- stomach ulcers (e.g. cimetidine);
- relief of pain (e.g. aspirin, ibuprofen, naproxen, indomethacin or other medicines known as non steroidal anti-inflammatory drugs);
- migraines (e.g. ergotamine or other ergot alkaloids);
- surgery (anaesthetic drugs);
- tuberculosis (rifampicin);
- malaria (e.g. mefloquine);
- gout (sulfapyrazone).

Slow-Trasicor Tablets with food, drink and alcohol

It is advisable not to drink alcohol whilst taking Slow-Trasicor Tablets as it may increase the effect of your medicine. Drinking large amounts of caffeine and smoking a high number of cigarettes may oppose the beneficial effects of Slow-Trasicor Tablets.

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. Oxprenolol passes into breast milk, therefore breast-feeding is not recommended whilst taking Slow-Trasicor Tablets.

Driving and using machines

You can drive while being treated with Slow-Trasicor Tablets but do not drive until you know how they affect you. They may make you feel dizzy, tired or affect your vision; if they affect you in this way, do not drive or operate any machinery.

Slow-Trasicor Tablets contain lactose

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 Slow-Trasicor Tablets

Always take Slow-Trasicor Tablets exactly as your doctor has told you. You should check with your doctor if you are not sure.

Swallow your tablets whole with a drink of water. Do not crush or chew the tablets as this may affect their special slow-release system.

The recommended dosages of Slow-Trasicor Tablets are as follows:

Chest pain (angina)

160 mg to be taken once daily. The maximum daily dose is 320 mg.

High blood pressure (hypertension)

160 mg to be taken once daily. The maximum daily dose is 320 mg.

Older people

No special dose is required for older people, but any existing liver problems should be taken into account before taking Slow-Trasicor Tablets. Ask your doctor if you are not sure if this applies to you.

If you take more Slow-Trasicor Tablets than you should

If you take more Slow-Trasicor Tablets than you should contact your doctor or nearest hospital emergency department immediately. Take the container and any remaining tablets with you. Symptoms of overdose include low blood pressure, slower heart beat, low blood sugar, heart attack and other heart problems, shortness of breath, difficulty in breathing, being sick, loss of consciousness and fits. Muscle pain with blood in the urine may occur.

If you forget to take Slow-Trasicor Tablets

If you forget to take a dose, take the next dose at the usual time. DO NOT take a double dose.

If you stop taking Slow-Trasicor Tablets

Ask your doctor before stopping treatment with Slow-Trasicor Tablets. If you stop taking your tablets suddenly it may cause your condition to get worse.

4. Possible side effects

Like all medicines, Slow-Trasicor Tablets can cause side effects, although not everyone gets them.

If you notice:

- Itching or skin rashes;
- Difficulty in breathing or wheeziness.

Stop taking the medicine and seek medical advice immediately. These may be signs of an allergic reaction.

Other side effects may include:

Very common side effects (occurring in more than 1 in 10 patients)

- Dry mouth;
- Constipation.

Common side effects (occurring in between 1 in 10 and 1 in 100 patients)

- Tiredness;
- Dizziness;
- Headache;
- Depression;
- Heart failure;
- Low blood pressure;
- Coldness, numbness or tingling in your hands and feet;
- Feeling sick;
- Shortness of breath, difficulty in breathing or wheezing;
- Reduced sex drive or impotence.

Uncommon side effects (occurring in between 1 in 100 and 1 in 1000 patients)

- Sleeping problems and nightmares;
- A very slow heart beat;
- Diarrhoea;
- Being sick;
- Blurred vision;
- Irregular heart beat;
- Wind;
- Skin problems (an allergic skin reaction which may include reddening, itching or a rash).

Rare side effects (occurring in between 1 in 1000 and 1 in 10,000 patients)

- Hallucinations;
- Tiredness on exertion;

- Poor blood circulation which makes the toes and fingers numb and pale (Raynaud's phenomenon);
- Worsening of psoriasis;
- Dry or sore eyes.

Very rare side effects (occurring in less than 1 in 10,000 patients)

- A reduction in blood platelets which increases the risk of bruising or bleeding (thrombocytopenia).

Not known (side effect frequency cannot be estimated from the available data):

- Severe reduction in the number of white blood cells which makes infections more likely (agranulocytosis);
- Inflammation of blood vessel walls, leading to tissue death, fever, skin redness;
- Increased sugar levels in the blood or urine;
- Decreased sugar levels in the blood;
- Confusion, mood changes, changes in the way you think;
- Chest pain;
- Worsening of existing pain in legs (intermittent claudication);
- Stomach pain, indigestion;
- Obstruction of the urinary tract with symptoms such as weakness, lower back pain, problems passing urine (retroperitoneal fibrosis);
- Muscle pains, cramps or weakness;
- Joint pain;
- Skin rash, itching, increased sweating;
- Serious illness with blistering of the skin;
- Joint pain and swelling with fever, chest pain, tiredness, and "butterfly skin rash" (cutaneous lupus erythematosus reactivation);
- Fever;
- Increased levels of proteins found in the blood vessels called anti-nuclear antibodies.

Long-term treatment with Slow-Trasicor Tablets may affect the levels of some proteins in your body which transport fats around your body.

Treatment with Slow-Trasicor Tablets may hide the symptoms of low blood sugar levels or an over-active thyroid gland.

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 the Yellow Card Scheme, website: 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 Slow-Trasicor Tablets

Do not use Slow-Trasicor Tablets after the expiry date which is stated on the carton.

Keep your tablets in a dry place.

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

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 to protect the environment.

6. Contents of the pack and other information

What Slow-Trasicor Tablets contain

Slow-Trasicor Tablets contain 160 mg of the active ingredient oxprenolol hydrochloride.

They also contain the following inactive ingredients:

lactose, silicon dioxide, calcium stearate, methacrylic acid copolymer, glyceryl palmitostearate, magnesium stearate, cellulose HP-M-603 (hypromellose 3 cps), polysorbate, talc, titanium dioxide.

What Slow-Trasicor Tablets look like and contents of the pack

Slow-Trasicor Tablets are white, round, slightly biconvex with bevelled edges approximately 10.1 mm in diameter. They are impressed SLOW-TRASICOR on one side and blank on the other side.

Slow-Trasicor Tablets come in packs containing 28 tablets.

Marketing Authorisation Holder and Manufacturer

Amdipharm UK Limited
Capital House, 85 King William Street, London EC4N 7BL, UK.

This leaflet was last revised in April 2016.