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PATIENT INFORMATION LEAFLET

TRANTALOL ATENOLOL 25 MG TABLETS,
TRANTALOL ATENOLOL 50 MG & 100 MG TABLETS
Atenolol

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.
- 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. What Trantalol Atenolol tablets are and what they are used for
2. Before you take Trantalol Atenolol tablets
3. How to take Trantalol Atenolol tablets
4. Possible side effects
5. How to store Trantalol Atenolol tablets
6. Further information

1. WHAT TRANTALOL ATENOLOL TABLETS ARE AND WHAT THEY ARE USED FOR

Trantalol Atenolol tablets contain the active ingredient atenolol, which belongs to a group of medicines known as beta-blockers. These medicines make your heart beat more slowly and with less force.

Trantalol Atenolol tablets are used to:

- help prevent chest pain (angina)
- protect the heart during and after a heart attack
- help prevent another heart attack from happening.
- treat high blood pressure
- treat irregular heart rhythms

2. BEFORE YOU TAKE TRANTALOL ATENOLOL TABLETS

Do NOT take the tablets if you:

- are allergic (hypersensitive) to atenolol or any of the other ingredients in the tablets (see Section 6 and end of Section 2)
- have ever had any of the following heart problems:
 - o heart failure which is not under control
 - o second- or third-degree heart block (a condition which may be treated by a pacemaker)
 - o very slow or very uneven heartbeats, very low blood pressure or very poor circulation.
- have a tumour in your adrenal glands (phaeochromocytoma) that is not being treated. This is usually near your kidney and can cause high blood pressure.
- have been told that you have higher than normal levels of acid in your blood (metabolic acidosis).

Do not take Trantalol Atenolol if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Trantalol Atenolol.

Take special care

Talk to your doctor before taking these tablets if you have:

- ever had an allergic reaction, for example, to insect stings – you may not respond to adrenaline
- asthma, wheezing or any other similar breathing problems or if you have had them in the past – these tablets may constrict the airways. If this happens stop taking the tablets and use a bronchodilator if necessary
- a type of chest pain (angina) called Prinzmetal's angina
- poor blood circulation or controlled heart failure
- first-degree heart block
- diabetes. Your medicine may change how you respond to having low blood sugar. You may feel your heart beating faster.
- thyrotoxicosis (a condition caused by an overactive thyroid gland) – these tablets may mask this condition
- symptoms caused by a reduced heart rate as a result of taking the tablets, as you may need to have your dose reduced
- ischaemic heart disease – do not stop taking the tablets suddenly
- kidney problems. You may need to have some check-ups during your treatment
- psoriasis (a skin condition).

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Trantalol Atenolol.

Taking other medicines

Please tell your doctor if you are taking, or have recently taken any other medicines, including medicines obtained without a prescription and herbal medicines. This is because Trantalol Atenolol can affect the way some other medicines work and some medicines can have an affect on Trantalol Atenolol. Particularly if you are taking:

- Isoprenaline, verapamil, diltiazem, hydralazine, guanethidine, reserpine and nifedipine (for high blood pressure or chest pain). These should not be taken for 48 hours before or after taking atenolol
- Diuretics (water-tablets)
- Phenobarbital (used to help you sleep)
- Disopyramide, chloroform, lignocaine, procainamide, isoprenaline, quinidine, amiodarone (for an uneven heartbeat)
- Cimetidine (for the treatment of stomach ulcer)
- Any phenothiazine medicine, such as chlorpromazine (for mental disorders)
- Digoxin (for heart failure)
- Noradrenaline or adrenaline (a heart stimulant)
- Ibuprofen or indomethacin (for pain and inflammation)
- Insulin or medicines that you take by mouth for diabetes
- Clonidine (for high blood pressure or migraine). If you are taking clonidine and atenolol together, do not stop taking clonidine unless your doctor tells you to do so. If you have to stop taking clonidine, your doctor will give you careful instructions about how to do it
- medicines to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy).

Operations

If you go into hospital to have an operation tell the anaesthetist and medical staff that you are taking atenolol. This is because you can get low blood pressure (hypotension) if you are given certain anaesthetics while you are taking Trantalol Atenolol. These tablets should be stopped 24 hours before surgery.

Taking Trantalol Atenolol tablets with food and drink.

Do not drink alcohol whilst taking these tablets.

Pregnancy and breast-feeding

Tell your doctor if you are pregnant, think you may be pregnant or are planning to become pregnant, or if you are breast-feeding. Trantalol Atenolol tablets should only be taken by pregnant or breast-feeding women if advised to by a doctor because they may harm the baby.

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy, or if you are breast-feeding.

Driving and using machinery

Trantalol Atenolol tablets are unlikely to affect your ability to drive or use machinery. Occasionally people feel dizzy or tired; if this happens to you, do not drive or use machinery and ask your doctor for advice.

Important information about some of the ingredients of this medicine

Trantalol Atenolol tablets 50 mg and 100 mg 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.

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3. HOW TO TAKE TRANTALOL ATENOLOL TABLETS

Always take the tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure about the dose you should take.

- Swallow the tablet whole with a drink of water
- Try to take the tablet at the same time each day

Your doctor will advise your dose. You should notice an effect after one to two weeks of treatment. Your doctor may also give you a diuretic medicine with these tablets.

Adults

To treat high blood pressure (hypertension): 50 mg to 100 mg a day.

To treat chest pain (angina): 50 mg to 100 mg a day or 50 mg twice a day.

The early treatment of a heart attack (myocardial infarction): 50 mg twice a day or 100 mg once a day.

To treat uneven heartbeats (arrhythmias): 50 mg to 100 mg a day.

Protection after a heart attack: 50 mg to 100 mg a day.

Elderly patients

Your dose may be reduced, particularly if you have problems with your kidneys. Your doctor will advise you.

Patients with severe kidney problems

Your dose may be reduced; your doctor will advise you.

Children

This medicine must not be given to children.

If you take more tablets than you should

If you have taken more tablets than you should, contact your doctor immediately or go to your nearest hospital accident and emergency department. Take this leaflet and/or the bottle with you. Symptoms of overdose include slow heartbeat, low blood pressure, poor circulation and difficulty breathing.

If you forget to take a dose

If you forget to take a dose, take one as soon as you remember, unless it is nearly time to take the next one. Take the remaining doses at the correct time. Do not take a double dose to make up for a missed dose.

If you stop taking the tablets

Do not stop taking these tablets without asking your doctor first. In some cases you may need to reduce the dose gradually.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Trantalol Atenolol tablets can cause side effects, although not everybody gets them.

STOP taking Trantalol Atenolol tablets and **seek medical help immediately** if you have any of the following which may be signs of an **allergic reaction**:

- difficulty breathing or swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised bumps.

The following side-effects may be experienced:

Common (affects less than 1 in 10 people)

- You may notice that your pulse rate becomes slower while you are taking the tablets. This is normal, but if you are concerned please speak to your doctor
- Cold hands and feet
- Feeling sick (nausea)
- Diarrhoea
- Feeling tired.

Uncommon (affects less than 1 in 100 people)

- Disturbed sleep
- Raised liver enzymes.

Rare (affects less than 1 in 1,000 people)

- Heart block (which can cause an abnormal heart beat, dizziness, tiredness or fainting)
- Numbness and spasm in your fingers which is followed by warmth and pain (Raynaud's disease)
- Mood changes
- Feeling confused
- Tingling of your hands
- Disturbances of vision
- Skin rash
- Changes in personality (psychoses) or hallucinations
- Dizziness (particularly when standing up)
- Being unable to get an erection (impotence)
- Reduced numbers of platelets in your blood (this may make you bruise more easily)
- Purplish marks on your skin
- Jaundice (causing yellowing of your skin or the whites of your eyes)
- Liver damage including blocked bile ducts.

Very rare (affects less than 1 in 10,000 people)

- Changes to some of the cells or other parts of your blood. Your doctor may take blood samples every so often to check whether Trantalol Atenolol has any effect on your blood.

Conditions that may get worse

If you have any of the following conditions, they may get worse when you start to take your medicine. This happens rarely, affecting less than 1 in 1,000 people.

- Psoriasis (a skin condition)
- Being short of breath or having swollen ankles (if you have heart failure)
- Asthma or breathing problems
- Poor circulation.

Not Known:

Lupus like syndrome (a disease where the immune system produces antibodies that attacks mainly skin and joints).

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 TRANTALOL ATENOLOL TABLETS

Keep out of the reach and sight of children. Do not use the tablets after the expiry date (EXP) which is stated on the label or carton. The expiry date refers to the last day of that month. Note: 25 mg tablets: Do not store above 25°C. 50 mg tablets and 100 mg tablets: Do not store above 25°C. Store in the original container. 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. FURTHER INFORMATION

Trantalol Atenolol tablets contain:

- the **active ingredient:** atenolol 25 mg, 50 mg or 100 mg per tablet
- **other ingredients:**

25 mg tablet: gelatin, magnesium carbonate, magnesium stearate, microcrystalline cellulose, maize starch, sodium laurilsulfate and talc.

50 mg and 100 mg tablets: lactose monohydrate (see also end of Section 2 for further information on lactose), magnesium stearate, microcrystalline cellulose, croscarmellose sodium, colloidal anhydrous silica. The 50 mg and 100 mg tablets have a coating which contains carnauba wax, opadry OY-S 58905 (hypromellose, titanium dioxide –E171, macrogol and talc).

What Trantalol Atenolol tablets look like and contents of the pack

Trantalol Atenolol 25 mg tablets are white, round tablets with a breakline on one side; the 50 mg and 100 mg tablets are film-coated and have a mark on the other side: 50 mg is marked with "1U1" and 100 mg is marked with "2U1".

The tablets are provided in plastic containers or blister packs. The 25 mg tablets are available in packs of 28, 30, 100 and 250 tablets; not all pack sizes may be marketed. The 50 mg and 100 mg tablets are available in packs of 28, 30, 100, 250, 500 and 1,000 tablets; not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland

PA 281/83/3 25 mg tablet
PA 281/83/1 50 mg tablet
PA 281/83/2 100 mg tablet

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