Rosemont®

Package Leaflet: Information for the user

Atenolol 25mg/5ml Sugar Free Oral Solution

atenolol

(referred to as "Atenolol Solution" throughout the text)

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

1. What Atenolol Solution is and what it is used for

Atenolol Solution contains atenolol which is a beta-blocker.
It is used to:
- treat high blood pressure (hypertension)
- treat heart rhythm changes (arrhythmias)
- prevent chest pain (angina)
- protect the heart in the early treatment after a heart attack (myocardial infarction).

2. What you need to know before you take Atenolol Solution

Do not take Atenolol Solution:
- if you are allergic to atenolol or to any of the other ingredients of this medicine (listed in section 6)
- if you have ever had any of the following heart problems:
  - heart failure which is not well controlled (this usually makes you breathless and causes your ankles to swell)
  - second or third-degree heart block (this is usually corrected with a pacemaker)
  - irregular or slow heartbeat
  - very low blood pressure
  - very poor blood circulation
- if you have an untreated tumour in your adrenal glands (phaeochromocytoma). This tumour lies near your kidneys and can cause high blood pressure
- if you have higher than normal levels of acid in your blood (metabolic acidosis)
- if you have severe problems with blood circulation in your limbs
- **Do not take this medicine if you have wheezing or asthma.**

If any of the above apply to you, speak to your doctor or pharmacist.

Warnings and precautions
Talk to your doctor or pharmacist before taking Atenolol Solution, if you have:
- or have ever had asthma, wheezing or any other similar breathing problems (reversible obstructive airways disease). Do not take this medicine without first checking with your doctor
- severe allergic reactions to some allergens, for example to insect stings, animal fur as the usual dose of adrenaline may not work
- well-controlled heart failure
- a type of angina (chest pain) called Prinzmetal's angina
- poor blood circulation or any problems with circulation in your limbs
- first-degree heart block
- diabetes. Atenolol Solution may mask the symptoms of low blood sugar such as an increase in heartbeat. Atenolol could also increase the risk of severe hypoglycaemia when used with certain type of antidiabetic drugs called sulfonylureas (e.g. gliquidone, gliclazide, glibenclamide, glipizide, glimepiride or tolbutamide)
- thyrotoxicosis (a condition caused by an overactive thyroid gland). Atenolol Solution may hide the symptoms of thyrotoxicosis
- kidney problems
or if you are
- elderly - you may need to start on a lower dose.

Other medicines and Atenolol Solution
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines may be affected by Atenolol Solution or they may affect how well Atenolol Solution will work. Tell your doctor or pharmacist if you are taking:
- clonidine (for high blood pressure or migraine). If you are taking clonidine and Atenolol Solution 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 for high blood pressure or chest pain (calcium channel blockers) e.g. verapamil, diltiazem and nifedipine, as this may result in severe low blood pressure, slow heartbeat or heart failure
- digoxin (for heart conditions)
- medicines for irregular heartbeat (e.g. disopyramide, quinidine, amiodarone)
- adrenaline, also known as epinephrine (a medicine that stimulates the heart)
- Insulin or medicines that you take by mouth for diabetes such as drugs called sulfonylureas (e.g. gliquidone, gliclazide, glibenclamide, glipizide, glimepiride or tolbutamide)
- anti-inflammatory medicines (e.g. ibuprofen, indometacin)
- medicines to treat nose or sinus congestion or other cold remedies (including those you can buy in a pharmacy).

If you go into hospital or to the dentist to have an **operation**, tell the anaesthetist or medical staff that you are taking Atenolol Solution. You may need to stop taking Atenolol Solution the day before. Your doctor will advise you as you can get low blood pressure (hypotension) if you are given certain anaesthetics while you are taking Atenolol Solution.

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.
Atenolol Solution can be passed to your unborn or breast-fed baby. DO NOT take Atenolol Solution if you are pregnant, planning to become pregnant or if you are breast-feeding unless advised to by your doctor, especially if you are less than 28 weeks pregnant.
Ask your doctor for advice before taking any medicine.

Driving and using machines
Atenolol Solution may cause dizziness or tiredness. If this occurs do not drive, use machinery, or perform any tasks that may require you to be alert.

Atenolol Solution contains sorbitol, propylene glycol, methyl hydroxybenzoate and propyl hydroxybenzoate, sodium and ethanol (alcohol)
- **sorbitol**
  This medicine contains 5.32g sorbitol in each 20ml (four 5ml spoonfuls) which is equivalent to 266mg/ml.
  Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.
- **propylene glycol**
  This medicine contains 1g propylene glycol in each 20ml (four 5ml spoonfuls) which is equivalent to 50mg/ml.
  If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine. If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.
- **methyl hydroxybenzoate and propyl hydroxybenzoate**
  These may cause allergic reactions (possibly delayed).
- **sodium**
  This medicine contains 32.8mg sodium (main component of cooking/table salt) in each 20ml (four 5ml spoonfuls) solution. This is equivalent to 1.64% of the recommended daily intake of sodium for an adult.

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- **ethanol (alcohol)**
  This medicine contains 2.25mg of alcohol (ethanol) in each 5ml, which is equivalent to 0.45mg/ml. The amount in 5ml dose of this medicine is equivalent to less than 1ml beer or 1ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to take Atenolol Solution

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Take the solution with or without food, whichever you prefer.
- Drinking **alcohol** while taking this medicine may cause your blood pressure to drop.

The recommended dose is
Adults:
- **High blood pressure (hypertension):** the usual dose is 10ml to 20ml (two to four 5ml spoonfuls) once a day.
- **Chest pain (angina):** the usual dose is 20ml (four 5ml spoonfuls) once a day or 10ml (two 5ml spoonfuls) twice a day.
- **Irregular heartbeats (arrhythmias):** the usual dose is 10ml to 20ml (two to four 5ml spoonfuls) once a day.
- **Early treatment of a heart attack (myocardial infarction):** following initial treatment by a doctor, the usual dose is 20ml (four 5ml spoonfuls) once a day.
  Your doctor will monitor you regularly for low heart rate (pulse 50-55 beats per minute at rest) and may reduce the dose.
  Elderly: your doctor may lower the dose, particularly if you have kidney problems.
  Children: this medicine is NOT suitable for children.
  Patients with severe kidney problems: if your kidneys are not working properly, your doctor may lower the dose.

If you take more Atenolol Solution than you should
If you take more solution than you should you may get wheezy and feel very tired, dizzy or become unconscious.
1. Tell your doctor, pharmacist or nearest hospital casualty department immediately.
2. Take the bottle and any remaining solution with you so that people can see what you have taken.
3. Do this even if you feel well.

If you forget to take Atenolol Solution
If you forget to take a dose, take it as soon as you remember, but if it is almost time for your next dose, skip the forgotten dose and continue as usual.
Do not take a double dose to make up for a forgotten dose.
If you stop taking Atenolol Solution
Stopping this medicine suddenly may cause:
- chest pain
- fast or irregular heartbeat
- general feeling of discomfort or illness or weakness
- headache
- shortness of breath (sudden)
- sweating
- trembling.

Do NOT stop taking this medicine suddenly. Talk to your doctor if you want to stop taking Atenolol Solution. Your doctor will explain how to reduce your dose slowly over 1 to 2 weeks.
Do not let yourself run out of medicine especially over the weekend or on holidays.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
STOP taking the solution and **seek medical help immediately** if you have any of the following **allergic reactions:**
- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised lumps.

Seek immediate medical attention if you have any of the following symptoms:
Rare (may affect less than 1 in 1000 people)
- signs of heart block (dizziness, abnormal heartbeat, tiredness or fainting)
- fainting, especially when standing up from a sitting or lying position
- pinpoint red spots on the skin, unusual purple bruise like rash on the skin or in the mouth, unusual or heavy bleeding
- changes in personality (psychoses).

Tell your doctor if you get any of the following side effects:
Common side effects (may affect less than 1 in 10 people)
- cold hands and feet
- slow or irregular heartbeat
- problems with digestion or bowels
- feeling tired

Uncommon side effects (may affect less than 1 in 100 people)
- disturbed sleep

Rare side effects (may affect less than 1 in 1000 people)
- dry mouth
- mood changes
- dry eyes, problems with vision
- headache
- nightmares, hallucinations
- dizziness
- confusion
- shortness of breath and swollen ankles
- tingling or numbness in arms and legs
- hair loss
- rash which looks like psoriasis (red or silver-white scaly patches of skin)
- light-headedness or dizziness when standing up from a sitting or lying position
- sore leg muscles which may cause you to 'limp' when walking
- numbness and spasm in your fingers which is followed by warmth and pain (Raynaud's disease)
- yellowing of your skin or eyes
- asthma
- difficulty getting an erection.

Not known
- Lupus-like syndrome (a disease where the immune system produces antibodies that attacks mainly skin and joints)
- Depression

Conditions that may get worse
If you have the following conditions they may get worse when you start taking Atenolol Solution:
- asthma or breathing problems
- psoriasis (red or silver-white scaly patches of skin)
- poor blood circulation
- heart failure (shortness of breath, swollen ankles).

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 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 Atenolol Solution

- 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 bottle label and on the carton. The expiry date refers to the last day of that month.
- Do not use after 30 days from the date of first opening.
- Do not store above 25°C. Store in the original container. Do not refrigerate or freeze.
- 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.

6. Contents of the pack and other information

What Atenolol Solution contains
- The active substance is atenolol (25mg per 5ml).
- The other ingredients are:
  sorbitol (E420), propylene glycol (E1520), saccharin sodium, methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), citric acid monohydrate, trisodium citrate dihydrate, lemon and lime flavour (containing ethanol), and purified water. (See end of Section 2 for further information on sorbitol, sodium, ethanol, propylene glycol, methyl hydroxybenzoate and propyl hydroxybenzoate).

What Atenolol Solution looks like and contents of the pack
Atenolol Solution is a clear, colourless solution with an odour of lemon and lime.
It is available in amber glass bottles of 300 ml.

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