

APX-ATENOLOL

atenolol

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about APX-ATENOLOL. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking APX-ATENOLOL against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What APX-ATENOLOL is used for

APX-ATENOLOL belongs to a group of medicines called beta-blockers. It works by affecting the body's response to certain nerve impulses, especially in the heart. As a result, it decreases the heart's need for blood and oxygen and therefore reduces the amount of work the heart has to do. It widens the blood vessels in the body, causing blood pressure to fall. It also helps the heart to beat more regularly.

APX-ATENOLOL is used to:

- lower high blood pressure, which is also called hypertension
- prevent angina (chest pain)
- treat irregular heart rhythm or beat such as arrhythmia

- treat or prevent heart attacks, or reduce your risk of heart complications following a heart attack
- widen vessels in the heart which have narrowed

Hypertension:

Everyone has blood pressure. This pressure helps get your blood all around your body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. You may feel fine and have no symptoms, but if high blood pressure is not treated, it can lead to serious health problems. APX-ATENOLOL helps to lower your blood pressure.

Angina:

Angina is a pain or uncomfortable feeling in the chest, often spreading to the arms or neck and sometimes to the shoulders and back. This may be caused by too little blood and oxygen getting to the heart. The pain of angina is usually brought on by exercise or stress, but can also occur at rest. APX-ATENOLOL helps prevent angina. It is not used to relieve a sudden attack of angina.

Irregular heart beat (arrhythmia):

Irregular heart beat, also known as arrhythmia, means that there is a

disturbance of the heart's normal rhythm or beat. Arrhythmias may be caused by a number of factors, including some heart diseases, an overactive thyroid gland, or chemical imbalances. APX-ATENOLOL helps restore the heart's normal rhythm.

Reducing heart complications after heart attack:

After a heart attack there is a chance of developing arrhythmias or of further heart attacks occurring. APX-ATENOLOL helps prevent these conditions from occurring.

APX-ATENOLOL may be either used alone or in combination with other medicines to treat your condition.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

APX-ATENOLOL is not recommended for use in children, as there have been no studies of its effects in children.

This medicine is available only with a doctor's prescription.

There is no evidence that APX-ATENOLOL is addictive.

Before you take it

When you must not take it

Do not take APX-ATENOLOL if:

1. **you have an allergy to atenolol or any of the ingredients listed at the end of this leaflet, or to**

any other beta-blocker medicine.

2. **you have or have had asthma (difficulty in breathing, wheezing and coughing), bronchitis or other lung problems in the past.**
3. **you have the following conditions:**
 - **a history of allergic problems, including hay fever.** Symptoms of an allergy may include: rash, itching, watery eyes or sneezing.
 - **low blood pressure** (hypotension)
 - **a very slow heart beat** (less than 45-50 beats/minute)
 - **certain other heart conditions such as heart failure**
 - **phaeochromocytoma** (a rare tumour of the adrenal gland) which is not being treated already with other medicines.
 - **you have too much acid in your blood, also called metabolic acidosis**
 - **a severe blood vessel disorder causing poor circulation in the arms and legs.**
 - **too much acid in your blood (metabolic acidosis)**
4. **you are receiving:**
 - **certain anaesthetics for medical or dental procedures**
 - **certain heart medicines, called calcium channel blockers or calcium antagonists, such as verapamil**
 - **emergency treatment for shock or severely low blood pressure.**
5. **you are pregnant or intend to become pregnant.**

Like most beta-blocker medicines, APX-ATENOLOL is not recommended for use during pregnancy.

6. **you are breast-feeding or plan to breast-feed.**

APX-ATENOLOL passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

If you are not sure whether any of these apply to you, check with your doctor.

Do not take APX-ATENOLOL if the packaging is torn or shows signs of tampering.

Do not take APX-ATENOLOL if the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure whether you should start taking APX-ATENOLOL, contact your doctor.

Before you start to take it

Tell your doctor if:

1. **you have any allergies to:**

- any other medicine including eye drops or other beta-blocker medicines
- any other substances, such as foods, preservatives or dyes
- insect stings

APX-ATENOLOL may make allergies worse or make them harder to treat.

2. **you are pregnant or intend to become pregnant.**
3. **you are breast-feeding or plan to breast-feed.**
4. **you have or have had any medical conditions, especially the following:**

- heart problems
- diabetes
- an overactive thyroid gland called hyperthyroidism
- kidney problems
- any blood vessel disorders causing poor blood circulation in the arms and legs

If you have not told your doctor about any of the above, tell them before you take APX-ATENOLOL.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a

prescription from your pharmacy, supermarket or health food shop.

Some medicines and APX-ATENOLOL may interfere with each other.

These include:

- other beta-blocker medicine
- medicines used to treat high blood pressure, angina or an irregular heart beat, such as verapamil or clonidine
- medicines used to treat other heart problems
- insulin and other medicines used to treat diabetes
- medicines used to treat arthritis, pain, or inflammation, for example indomethacin and ibuprofen
- medicines commonly used during surgery or in emergency situations such as dopamine, adrenaline, noradrenaline and certain anaesthetics.

These medicines may be affected by APX-ATENOLOL, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking APX-ATENOLOL.

How to take it

How much to take and how to take it

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

Certain people (eg. elderly patients or those with kidney problems) may require lower doses.

Hypertension:

Adults – The usual daily dose is between 50 mg (1 tablet) up to 200 mg (4 tablets). If your dose is 100 mg or less, take your dose once a day. If your dose is greater than 100 mg, take half of your dose in the morning and the rest in the evening.

Angina or Arrhythmia (irregular heart beat):

Adults – The usual daily dose is between 50 mg (1 tablet) up to 100 mg (2 tablets), which can be taken as a single dose or half the dose in the morning and the rest in the evening.

Heart attack:

The usual dose is 50 mg (1 tablet) to 100 mg (2 tablets) daily for 1 – 3 years following a heart attack for 1 – 3 years.

The doses mentioned may be given after the condition (eg. arrhythmia, heart attack) is brought under control.

APX-ATENOLOL is not recommended for children.

When to take it

Swallow APX-ATENOLOL with a glass of water.

It does not matter if you take it before or after food.

Take your tablet(s) at the same time everyday.

How long to take it

APX-ATENOLOL helps control your high blood pressure, angina and irregular heart beat, but does not cure it. Therefore APX-ATENOLOL must be taken every day. Continue taking it for as long as your doctor prescribes.

Do not stop taking APX-ATENOLOL without checking with your doctor.

Your doctor may want you to gradually reduce the amount of APX-ATENOLOL you are taking 2

weeks before stopping completely. This may help reduce the possibility of your angina worsening or other heart complications from occurring.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to casualty at your nearest hospital, if you think that you or anyone else may have taken too much APX-ATENOLOL. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep these telephone numbers handy.

If you take too much APX-ATENOLOL, you may feel faint or dizzy or you may find it difficult to breathe.

While you are using it

Things you must do

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking APX-ATENOLOL.

If you become pregnant while taking APX-ATENOLOL, tell your doctor immediately.

If you have a severe allergic reaction to foods, medicines or insect stings, tell your doctor immediately.

If you have a history of allergies, there is a chance that APX-ATENOLOL may cause allergic reactions to be worse and harder to treat.

If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.

APX-ATENOLOL may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar, called hypoglycaemia, such as fast heart beat. APX-ATENOLOL may make low blood sugar last longer. Your doses of diabetic medicines, including insulin, may need to change.

If you have angina and continue to have angina attacks or have more of them while you are taking this medicine, tell your doctor.

APX-ATENOLOL is used to help prevent angina, so your angina attacks should become less severe and occur less often.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

You may feel light-headed or dizzy when you begin to take APX-ATENOLOL. This is because your blood pressure is falling suddenly. If this problem gets worse or continues, talk to your doctor.

To avoid symptoms of low blood pressure, here are some hints that may help:

- stand up slowly from a sitting or lying position to help your body get used to the change in position and blood pressure
- if you feel dizzy, sit or lie down until you feel better
- if you feel faint, bend forward with your head between your knees

- take extra care when exercising, driving or standing for long periods, especially in hot weather. Drink plenty of fluids, especially if you sweat a lot.

Make sure you drink enough water during exercise and hot weather when you are taking APX-ATENOLOL, especially if you sweat a lot.

If you do not drink enough water while taking APX-ATENOLOL, you may feel faint, light-headed or sick. This is because your blood pressure is dropping suddenly. The recommended healthy minimum water intake is 6 – 8 glasses daily.

If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking APX-ATENOLOL.

Your blood pressure may drop suddenly.

If you have to have any medical tests while you are taking APX-ATENOLOL, tell your doctor. APX-ATENOLOL may affect the results of some tests.

If you are about to be started on any new medicines, remind your doctor or pharmacist.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking APX-ATENOLOL.

Things you must not do

Do not stop taking APX-ATENOLOL without checking with your doctor.

Your doctor may want you to gradually reduce the amount of APX-ATENOLOL you are taking before stopping completely. This may help reduce the possibility of your angina worsening or other heart complications from occurring.

Do not give your medicine to anyone else even if they have the same condition as you.

Do not use it to treat any other complaints unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how APX-ATENOLOL affects you.

As with other beta-blocker medicines, APX-ATENOLOL may cause dizziness, light-headedness, tiredness and drowsiness in some people. Make sure you know how you react to APX-ATENOLOL before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or light-headedness may be worse.

Dress warmly during cold weather, especially if you will be outside for a long time (for example, when playing winter sports).

APX-ATENOLOL, like other beta-blocker medicines, may make you more sensitive to cold temperatures, especially if you have blood circulation problems. Beta-blockers tend to decrease blood circulation in the skin, fingers and toes.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking APX-ATENOLOL.

If you get any side effects, do not stop taking APX-ATENOLOL without first talking to your doctor.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- stomach upsets such as diarrhoea, constipation,

abdominal pain or heartburn (indigestion)

- dry mouth, change in taste sensation
- dizziness, headache or buzzing or ringing in the ears
- slow or irregular heart beat
- dry eyes, problems with vision
- runny or blocked nose
- difficulty sleeping, nightmares, vivid dreams
- skin reactions (e.g. rash, itching, worsening of psoriasis)
- increased hair loss
- tingling, 'pins and needles' or walking unsteadily
- sexual problems

These are the more common side effects of APX-ATENOLOL. For the most part these have been mild.

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

- confusion or disorientation
- depression or mood changes or a worsening of these
- unusual thoughts, hallucinations (seeing, feeling or hearing things that are not there)
- light-headedness or fainting which may be due to low blood pressure
- yellowing of the skin and/or eyes (jaundice)

These are serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to casualty at your nearest hospital:

- shortness of breath, sometimes with tiredness, weakness and reduced ability to exercise, swelling of the feet or legs due to fluid buildup
- chest pain, changes in heart rate (fast, slow or irregular), palpitations
- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or

- breathing, which may be signs of a serious allergic reaction
- chest tightness, wheezing, rattly breathing
 - bleeding or bruising more easily than normal

These are very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

After using it

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they will not keep well.

Keep the tablets in a cool dry place where the temperature stays below 25 degrees Celsius. Protect from light.

Do not store APX-ATENOLOL of any other medicine in the bathroom or near the sink.

Do not leave APX-ATENOLOL in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking APX-ATENOLOL or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

APX-ATENOLOL tablets are white, film coated, biconvex and round with a breakline on one face and plain on the other face.

APX-ATENOLOL tablets are available in calendar packs or bottles (dispensing pack only) containing 30 tablets.

Ingredients

Each APX-ATENOLOL tablet contains 50 mg atenolol as the active ingredient.

In addition, each tablet contains:

- microcrystalline cellulose
- pregelatinised maize starch,
- sodium lauryl sulfate,
- sodium starch glycollate,
- colloidal anhydrous silica,
- magnesium stearate,
- Hypromellose
- opadry white Y-1-7000B (containing hypromellose, titanium dioxide, Macrogol 400 and indigo carmine aluminium lake CI 73015).

APX-ATENOLOL does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

APX-ATENOLOL is supplied in Australia by:

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

The Australian Registration number for APX-ATENOLOL 50 mg tablets is:

AUST R 332998
AUST R 332999 (bottle).

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