APX-ATENOLOL

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using APX-ATENOLOL?

APX-ATENOLOL contains the active ingredient atenolol. APX-ATENOLOL is used to lower high blood pressure, which is called hypertension, prevent angina, treat irregular heart rhythm or beat called arrhythmias and treat heart attacks, or reduce your risk of heart complications following a heart attack. For more information, see Section 1. Why am I using APX-ATENOLOL? in the full CMI.

2. What should I know before I use APX-ATENOLOL?

Do not use if you have ever had an allergic reaction to APX-ATENOLOL or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use APX-ATENOLOL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APX-ATENOLOL and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use APX-ATENOLOL?

- Follow all directions given to you by your doctor or pharmacist carefully.
- If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

More instructions can be found in Section 4. How do I use APX-ATENOLOL? in the full CMI.

5. What should I know while using APX-ATENOLOL?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using APX-ATENOLOL. • Attend all of your doctor's appointments so that your progress can be checked.
Things you should not do	• Do not stop taking APX-ATENOLOL or change the dose without checking with your doctor. • Do not take any new medicines with APX-ATENOLOL, unless your doctor has told you to. • Do not use APX-ATENOLOL to treat any other complaint unless your doctor tells you to. • Do not give APX-ATENOLOL to anyone else, even if their symptoms seem similar or they have the same condition as you
Driving or using machines	• 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 lightheaded.
Drinking alcohol	• Tell your doctor if you drink alcohol. • Alcohol may impact the effects of APX-ATENOLOL
Looking after your medicine	• Store below 25°C • Protect from light

For more information, see Section 5. What should I know while using APX-ATENOLOL? in the full CMI.

6. Are there any side effects?

Common side effects include: stomach upsets such as diarrhoea, constipation, abdominal pain or heartburn, 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 , skin reactions, cold fingers and toes, increased hair loss, tingling 'pins and needles' or walking unsteadily or sexual problems. Serious side effects include: confusion or disorientation, depression or mood changes or a worsening of these, unusual thoughts, hallucinations, light-headedness or fainting which may be due to low blood pressure or yellowing of the skin and/or eyes. Very serious side effects include: allergic

reaction. For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

APX-ATENOLOL

Active ingredient(s): *Atenolol*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APX-ATENOLOL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APX-ATENOLOL.**

Where to find information in this leaflet:

1. Why am I using APX-ATENOLOL?
2. What should I know before I use APX-ATENOLOL?
3. What if I am taking other medicines?
4. How do I use APX-ATENOLOL?
5. What should I know while using APX-ATENOLOL?
6. Are there any side effects?
7. Product details

1. Why am I using APX-ATENOLOL?

APX-ATENOLOL contains the active ingredient atenolol. 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 called hypertension
- prevent angina
- treat irregular heart rhythm or beat called arrhythmias
- treat heart attacks or reduce your risk of heart complications following a heart attack.

2. What should I know before I use APX-ATENOLOL?

Warnings

Do not use APX-ATENOLOL if:

- you are allergic to atenolol, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine. Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin or you may feel faint
- you have or have had asthma (difficulty in breathing, wheezing and coughing), bronchitis or other lung problems in the past.
- you have the following conditions:
  - o a history of allergic problems, including hay fever. Symptoms of an allergy may include rash, itching, watery eyes or sneezing.
  - o a very slow heartbeat (less than 45-50 beats/ minute)
  - o a severe blood vessel disorder causing poor circulation in the arms and legs
  - o certain other heart conditions
  - o phaeochromocytoma (a rare tumor of the adrenal gland) which is not being treated with other medicines
  - o low blood pressure (hypotension)
  - o too much acid in your blood (metabolic acidosis)
- you are receiving:
  - o certain anesthetics for medical dental procedures
  - o emergency treatment for shock or severely low blood pressure

Check with your doctor if you:

- have any other medical conditions, including:
  - o heart problems
  - o diabetes
  - o an over active thyroid gland called hyperthyroidism
  - o kidney problems
  - o circulation problems
- have any allergies to:
  - o any other medicine, including eye drops, or other beta-blocker medicines
  - o any other substances, such as foods, preservatives or dyes
  - o insect stings
- APX-ATENOLOL may make allergies worse or make them harder to treat.
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Do not take APX-ATENOLOL if you are pregnant or intend to become pregnant, are breastfeeding or intend to breastfeed.
Your doctor will discuss the possible risks and benefits of using APX-ATENOLOL during pregnancy and breast feeding.
APX-ATENOLOL passes into breast milk and may therefore affect the breast-fed baby.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with APX-ATENOLOL and how it works, and some medicines may be affected by APX-ATENOLOL.

These medicines include:

- other beta-blocker medicines
- medicines used to treat high blood pressure or angina
- medicine used to treat heart problems
- insulin and tablets used to treat diabetes such as drugs called sulfonylureas (e.g. gliquidone, gliclazide, glibenclamide, glipizide, glimepiride or tolbutamide)
- medicines used to treat arthritis, pain, or inflammation

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APX-ATENOLOL.

4. How do I use APX-ATENOLOL?

How much to take / use

- Follow all directions given to you by your doctor or pharmacist carefully.
- If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.
- Hypertension:
  o The usual dose is from 50mg (1 tablet) up to 200mg (4 tablets) of APX-ATENOLOL daily.
  o If your dose is 100mg or less, take it once a day. If you need to take more than 100mg (2 tablets), take half of your APX-ATENOLOL in the morning and the other half in the evening.
- Angina or Irregular Heartbeat:
  o The usual dose is from 50mg (1 tablet) up to 100mg (2 tablets) taken as a single dose or half the dose in the morning and half at night.
- Heart attack:
  o The usual dose is 50mg (1 tablet) of APX-ATENOLOL daily.
  o Certain people such as the elderly or those with kidney problems, may require a lower dose.
- Follow the instructions provided and use APX-ATENOLOL until your doctor tells you to stop.

When to take APX-ATENOLOL

- APX-ATENOLOL should be used at the same time everyday
- It does not matter if you take your APX-ATENOLOL before or after food.

How to take APX-ATENOLOL

- Swallow APX-ATENOLOL with a glass of water, during or immediately after a meal.

How long to take APX-ATENOLOL

- Take APX-ATENOLOL every day. Continue taking APX-ATENOLOL until your doctor advises you to stop.
  o APX-ATENOLOL helps treat your condition but does not cure it.
- Do not stop taking APX-ATENOLOL without checking with your doctor.
  o Your doctor may want you to gradually reduce the amount of APX-ATENOLOL you are taking. This should take place over a period of about 2 weeks before stopping completely. Do not stop suddenly as this may worsen your condition.
- Make sure you keep enough APX-ATENOLOL to last over weekends and holidays.

If you forget to use APX-ATENOLOL

APX-ATENOLOL should be used regularly at the same time each day.
If it is less than six hours from when you missed your dose, take it as soon as you remember, and then go back to taking your tablets at the same time you would normally.
If it is more than six hours since your last dose, skip the dose you missed and take your next dose when you would normally.

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

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

If you use too much APX-ATENOLOL

If you think that you have used too much APX-ATENOLOL, you may need urgent medical attention. If you take too much APX-ATENOLOL, you may feel faint or dizzy or you may find it difficult to breathe

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

5. What should I know while using APX-ATENOLOL?

Things you should do

Attend all of your doctor's appointments so that your progress can be checked.

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

If you are about to be started on any new medicines, tell your doctor, dentist or pharmacist that you are taking APX-ATENOLOL.

Call your doctor straight away if you:

- become pregnant while taking APX-ATENOLOL.
- have an allergic reaction to any foods, medicines or insect stings.
  o APX-ATENOLOL can cause allergic reactions to be worse and harder to treat.
- have diabetes and notices any blood sugar level changes
  o APX-ATENOLOL may affect your diabetes. It may hide the symptoms of low blood sugar levels, such as a fast heartbeat. It may also take longer for your blood sugar level to get back to normal even if you follow the usual treatment for diabetes. Your diabetic medicines may have to be changed or the doses adjusted. 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).
- continue to have angina attacks, or have more of them whilst taking APX-ATENOLOL
  o APX-ATENOLOL is used to help prevent angina, so your angina attacks should become less severe and occur less often.
- feel light-headed, dizzy or faint, and this problem gets worse or continues
  o Get up slowly when getting out of bed or standing up
  o You may feel light-headed or dizzy after taking APX-ATENOLOL. This is because your blood pressure is falling suddenly.
  o To help your body get used to the change in blood pressure, you may find the following hints useful:
- Stand up slowly when getting up from a chair or bed. This will allow 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, sit down and put your head between your knees.
- are having surgery (even at the dentist), tell your doctor or dentist that you are taking APX-ATENOLOL.
  o APX-ATENOLOL may affect some of the medicines used during surgery.
- have any medical tests while you are taking APX-ATENOLOL
  o APX-ATENOLOL may affect the results of some tests.

Things you must do

- Drink lots of water when exercising and during hot weather when taking APX-ATENOLOL, especially if you sweat a lot.
  o If you do not drink enough water while taking APX-ATENOLOL, you may feel faint, light-headed or sick. The recommended healthy minimum water intake is 6-8 glasses a day

Remind any doctor, dentist or pharmacist you visit that you are using APX-ATENOLOL.

Things you should not do

- Do not stop taking APX-ATENOLOL or change the dose without checking with your doctor.
- Do not take any new medicines with APX-ATENOLOL, unless your doctor has told you to.
- Do not use APX-ATENOLOL to treat any other complaint unless your doctor tells you to.
- Do not give APX-ATENOLOL to anyone else, even if their symptoms seem similar or they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APX-ATENOLOL affects you.

APX-ATENOLOL may cause dizziness, fatigue, light-headedness or faintness 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 lightheaded.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may impact the effects of APX-ATENOLOL.

Things to be careful of

Be careful not to over exercise when you first start taking APX-ATENOLOL.
It helps prevent angina resulting from physical activity and exercise. You may be tempted to exercise too much. Talk to your doctor about how much exercise you can do.

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

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

Looking after your medicine

- Protect from light
- Keep your tablets in the pack until it is time to take them.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away where the temperature stays below 25°C, away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

Less serious side effects

Less serious side effects	What to do
Gut-related: • stomach upsets such as diarrhoea, constipation, abdominal pain or heartburn (indigestion) **Respiratory or breathing-related:** • runny or blocked nose **Other:** • dry mouth, change in taste sensation • dizziness, headache or buzzing or ringing in the ears • slow or irregular heartbeat • dry eyes, problems with vision • difficulty sleeping, nightmares • skin reactions (e.g. rash, itching, worsening of psoriasis) • cold fingers and toes • increased hair loss • tingling, 'pins and needles' or walking unsteadily • sexual problems	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Neurological or brain-related: • 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	**Call your doctor straight away, if you notice any of these serious side effects.**
Other: • yellowing of the skin and/or eyes (jaundice)	

Very serious side effects

Very Serious side effects	What to do
Allergic reaction-related: • wheezing, chest tightness or difficulty breathing • swelling of the face, lips or throat **Other:** • unexplained bruising	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine. **Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

7. Product details

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

What APX-ATENOLOL contains

Active ingredient **(main ingredient)**	A**tenolol**
Other ingredients **(inactive ingredients)**	• 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 aluminum lake
Potential allergens	-

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

Do not take this medicine if you are allergic to any of these ingredients.

What APX-ATENOLOL looks like

APX-ATENOLOL 50 mg tablets are white, film coated, biconvex and round with a break line 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.

AUST R 332998
AUST R 332999 (bottle).

Who distributes APX-ATENOLOL

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121

www.arrotex.com.au

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