

## APO-Metoprolol Tablets

Contains the active ingredient metoprolol tartrate

### Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

#### What is in this leaflet

##### Read this leaflet carefully before taking your medicine.

This leaflet answers some of the common questions about metoprolol. It does not contain all the information. It does not take the place of talking to your doctor and pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

##### Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from [www.apotex.com.au](http://www.apotex.com.au).

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

#### What this medicine is used for

The name of your medicine is APO-Metoprolol tablets. It contains the active ingredient metoprolol.

It is used:

1. to treat high blood pressure, also called hypertension
2. to prevent a type of chest pain, also called angina
3. after a heart attack
4. to prevent migraine headaches.

##### 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.

##### How it works

###### Hypertension

Everyone has blood pressure. This pressure helps to move your blood around your body. Your blood pressure may be different at various times of the day, depending on how busy you are.

You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed. If high blood pressure is not treated it can lead to serious health problems, including stroke, heart disease and kidney failure.

There are usually no symptoms of hypertension. The only way of knowing that you have it 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. Metoprolol 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 it can also happen while you are resting.

Metoprolol helps to prevent angina from happening. It is not used to treat a sudden attack.

##### Reducing heart complications after heart attack

After a heart attack there is a chance of developing complications such as an irregular heart beat (also called an arrhythmia) or another heart attack.

Metoprolol helps to prevent these conditions from happening.

##### Migraine

This is a throbbing headache, usually affecting one side of the head and often accompanied by nausea, vomiting and sensitivity to light.

Metoprolol belongs to a group of medicines called beta-blockers. It works by affecting the body's response to some nerve impulses, especially in the heart. As a result, it decreases the heart's need for blood and oxygen and reduces the amount of work that the heart has to do. It also widens the blood vessels in the rest of the body.

Metoprolol can be used alone or in combination with other medicines to treat your condition.

Metoprolol is only available with a doctor's prescription.

There is no evidence that this medicine is addictive.

##### Use in children

Metoprolol is not recommended for use in children.

#### Before you take this medicine

##### When you must not take it

##### Do not take this medicine if:

- **You have or have had any of the following:**
  - sudden loss of consciousness sometimes
  - asthma, wheezing, difficulty breathing or other severe lung problems
  - a history of allergic problems, including hay fever
  - a very slow heartbeat, less than 45 to 50 beats per minute
  - low blood pressure
  - a severe blood vessel disorder causing poor circulation in the arms and legs, severe drop in blood pressure, dizziness, fast heartbeat, rapid and shallow breathing, cold clammy skin
  - phaeochromocytoma (a rare tumour of the adrenal gland) which is not already being treated with other medicines
  - sudden and oppressive chest pain, sign of heart attack
  - irregular heart beat (without functioning pacemaker)
  - heart disorders
  - swollen ankles and/or tiredness due to heart disease or certain other heart conditions
  - poor blood circulation in your limbs (for example, very cold, pale hands or feet, or pain in your leg muscles when you walk
  - shock.

**If you are not sure whether any of the above medical conditions apply to you, check with your doctor.**

- **You are hypersensitive to, or have had an allergic reaction to, metoprolol, any other beta-blocker medicine, or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

**If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

##### Before you start to take it

**Before you start taking this medicine, tell your doctor if:**

1. You have allergies to:
  - any other medicines, foods, dyes or preservatives
  - bee or wasp stings.Your doctor will want to know if you are prone to allergies. Beta-blocker medicines can make an allergic reaction worse.
2. You have or have had any medical conditions, especially the following:
  - diabetes
  - an overactive thyroid gland
  - kidney problems
  - liver problems
  - a heart attack
- chest pain when you are at rest, or certain types of angina, such as Prinzmetal angina or variant angina
- oculomucocutaneous syndrome (signs include severe conjunctivitis and skin rash and ear infection).
3. You are going to have an operation where an anaesthetic is used.
4. You are currently pregnant or you plan to become pregnant.

##### Immediately inform your doctor if you become pregnant.

Metoprolol should not be used throughout pregnancy, especially during the first 3 months of pregnancy, unless clearly necessary.

Metoprolol may affect your baby, especially if you take it in the last few days before your baby is born.

Your doctor can discuss the risks and benefits of taking this medicine during pregnancy.

5. You are currently breastfeeding or you plan to breastfeed.

The active ingredient in metoprolol passes into breast milk and there is a possibility that your baby could be affected.

##### Taking other medicines

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

Some medicines may interact with metoprolol. These include:

- other beta-blocker medicines
- other medicines used to treat high blood pressure such as calcium channel blockers, clonidine and hydralazine
- some medicines used to treat angina
- adrenaline or similar substances, which are often found in eye or nose drops, or in some cough and cold medicines
- other medicines used to treat irregular heart beat (arrhythmias)
- medicines for diabetes
- guanethidine, a medicine used to treat certain heart conditions
- some local and general anaesthetics used during surgery
- monoamine-oxidase inhibitor (MAOI) medicines
- warfarin, a medicine used to prevent blood clots
- non-steroidal anti-inflammatory drugs such as COX-2 inhibitors to relieve pain or inflammation
- indomethacin, a medicine for arthritis, pain or inflammation
- cimetidine, a medicine for stomach ulcers
- some antibiotics (e.g. rifampicin)
- some antivirals (e.g. ritonavir)
- some antihistamines (e.g. diphenhydramine)
- some antidepressant medications (e.g. fluoxetine, paroxetine or bupropion)
- some antifungals (e.g. terbinafine)
- ergot alkaloids, a class of medicines used in the prevention and treatment of migraine headaches
- dipyridamole, a medicine use to reduce the risk of blood clots.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with metoprolol.

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## How to take this medicine

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Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

### *How much to take*

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

### **High blood pressure:**

The usual dose is from 50 mg to 200 mg each day, either as a single dose or divided into two doses.

### **Angina:**

The usual dose is from 100 mg to 300 mg each day, divided into two or three doses.

### **After a heart attack:**

The usual dose is 200 mg each day, divided into two doses.

### **To prevent migraine:**

The usual dose is from 100 mg to 150 mg each day, divided into two doses (morning and evening).

### *How to take it*

Swallow the tablets whole with a full glass of water.

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

### *How long to take it*

**Continue taking metoprolol for as long as your doctor tells you.**

Metoprolol helps to control your symptoms but it does not cure your condition. Your doctor will check your progress to make sure the medicine is working and will decide how long your treatment should continue.

Talk to your doctor if you are not sure how long you need to take your medicine for.

Make sure you have enough to last over weekends and holidays.

### *If you forget to take it*

If it is almost time for your next dose, skip the missed dose and take your next dose at the usual time.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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

### *If you take too much*

**If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) for advice. Alternatively, go to Accident and Emergency at your nearest hospital.**

**Do this even if there are no signs or discomfort or poisoning. You may need urgent medical attention.**

Symptoms of an overdose may include feeling sick and vomiting, bluish skin and nails, very low blood pressure, slow heart beat, difficulty breathing, fainting, convulsions (fits), coma or death.

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## While you are taking this medicine

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### *Things you must do*

Tell your doctor, dentist or pharmacist that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests

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

This helps your doctor to give you the best treatment and to prevent unwanted side effects from happening.

**If you become pregnant while taking metoprolol, tell your doctor immediately.**

Your doctor can discuss with you the risks and benefits of taking it while you are pregnant.

**If you have an allergic reaction to a food, another medicine or an insect sting while you are taking metoprolol, tell your doctor immediately.**

There is a chance that metoprolol could make the allergic reaction worse or harder to treat.

**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 start to take metoprolol.

This is because your blood pressure is falling suddenly. If this problem doesn't go away, talk to your doctor.

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

- Stand up slowly 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, breathe deeply and 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.

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

Metoprolol may change how well your diabetes is controlled. It may also prevent some of the warning signs of low blood sugar, such as fast heart beat, and may make low blood sugar last longer. The dose of your diabetes medicines may need to be changed.

**If you plan to have surgery and will need an anaesthetic, tell your doctor or dentist that you are taking metoprolol.**

This will help your doctor to prevent unwanted side effects such as a sudden drop in blood pressure.

**Tell any other doctor, dentist, or pharmacist who treats you that you are taking metoprolol.**

### *Things you must not do*

**Do not:**

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Your doctor may want to gradually reduce the amount of metoprolol you are taking before stopping it completely. This helps to reduce the chance of your condition becoming worse or keep other unwanted heart problems from happening.

### *Things to be careful of*

**Be careful driving, operating machinery or doing jobs that require you to be alert while you are taking metoprolol until you know how it affects you.**

As with other beta-blocker medicines, metoprolol may cause dizziness, lightheadedness or decreased alertness in some people.

**If you have any of these symptoms, do not drive or do anything else that could be dangerous.**

**Be careful to dress warmly during cold weather, especially if you will be outside for a long time.**

Like other beta-blocker medicines, metoprolol may make you more sensitive to cold temperatures, especially if you have problems with your blood circulation. These medicines tend to decrease blood circulation in the skin, fingers and toes.

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## Possible side effects

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**Tell your doctor as soon as possible if you do not feel well while you are taking metoprolol or if you have any questions or concerns.**

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

If you are over 65 years of age, you may have an increased chance of getting side effects.

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

- tiredness, drowsiness, decreased alertness
- dizziness, spinning sensation (vertigo), light-headedness
- headache or other aches and pains
- difficulty sleeping, nightmares
- stomach ache or upset, nausea (feeling sick) or vomiting
- diarrhoea or constipation
- dry or irritated eyes, blurred vision
- dry mouth
- increased sweating
- runny or blocked nose
- abnormal triglycerides or cholesterol values, or liver function tests during treatment with metoprolol
- sleepiness during the day or troubled sleep

**Tell your doctor as soon as possible if you notice any of the following.**

These may be serious side effects and you may need medical attention.

- fainting
- depression or other changes in mood
- confusion or loss of memory
- buzzing or ringing in the ears, or other difficulty hearing
- problems with sexual function
- weight gain
- hair thinning
- worsening of psoriasis
- muscle cramps or painful joints
- a tingling sensation

**Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:**

- shortness of breath, sometimes with tiredness, weakness or reduced ability to exercise
- swelling of the feet or legs due to fluid build-up
- coldness, burning, numbness or pain in arms and legs
- chest pain
- pain behind the breastbone (different from angina)
- changes in heart rate (fast, slow, irregular)
- yellowing of the skin or eyes (jaundice), sometimes with pain in the abdomen
- constant "flu-like" symptoms (chills, fever, sore throat, aching joints, swollen glands, tiredness or lack of energy)
- unusual bleeding or bruising
- skin reactions (rash, itching, worsening of psoriasis)
- symptoms of sunburn (redness, itching, swelling, blistering) that happen much more quickly than normal
- abnormal thinking or hallucinations (seeing or hearing things that are not there)

Other side effects not listed above may occur in some patients.

### Allergic reactions

**If you think you are having an allergic reaction to metoprolol, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

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## Storage and Disposal

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### Storage

Keep your tablets in the original container until it is time to take them. If you take your medicine out of its original packaging it may not keep well.

**Keep your medicine in a cool dry place where the temperature will stay below 30°C.**

**Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep this medicine 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 this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

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## Product description

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### What APO-metoprolol looks like

Metoprolol 50 mg tablets are pink, round, biconvex film-coated tablets with notch break line on one side and '50' debossed on the other side;

A blister pack contains 10 tablets or 100 tablets.

Metoprolol 100 mg tablets are white to off white, round, biconvex film-coated tablets with notch break line on one side and '100' debossed on the other side;

A blister pack contains 10 tablets or 60 tablets.

\* Not all strengths, pack types and/or pack sizes may be available.

### Ingredients:

Metoprolol contains 50 mg or 100 mg of metoprolol tartrate as the active ingredient.

The tablets also contain the following in-active ingredients:

- Lactose monohydrate
- Cellulose- microcrystalline
- Sodium starch glycollate
- Silica-colloidal anhydrous
- Croscarmellose sodium
- Starch pregelatinised - maize
- Talc - purified
- Magnesium stearate
- Hypromellose
- Macrogol 400
- Titanium dioxide

- Iron oxide - red (50 mg only)

### Australian Registration Numbers:

APO-Metoprolol 50mg Tablets blister pack (Clear PVC/Al): AUST R 192766.

APO-Metoprolol 100mg Tablets blister pack (Clear PVC/Al): AUST R 192772.

### Sponsor

Apotex Pty Ltd  
16 Giffnock Avenue  
Macquarie Park NSW 2113

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