

# NOUMED METOPROLOL

*metoprolol tartrate tablets*

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some common questions about NOUMED METOPROLOL.

It does not contain all of 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 this medicine 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.

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### What NOUMED METOPROLOL is used for

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NOUMED METOPROLOL tablets contain the active ingredient metoprolol tartrate.

Metoprolol tartrate belongs to a group of medicines called beta-blockers, which are used to:

- lower high blood pressure (hypertension).
- prevent severe chest pain (angina pectoris).
- prevent heart attack (myocardial infarction) or its complications.
- prevent migraine headaches.

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 therefore reduces the amount of work the heart has to do. It also widens the blood vessels in the body, causing blood pressure to fall.

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

**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.

This medicine is not addictive.

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### Before you take it

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*When you must not take it*

**Do not take this medicine if you have an allergy to:**

- metoprolol tartrate, the active ingredient, or any of the inactive ingredients listed at the end of this leaflet under Product Description.
- any other similar medicines such as other beta-blockers.

Some of the symptoms of an allergic reaction may include shortness of breath; wheezing or difficulty in breathing; swelling of the face, lips tongue or other parts of the body; rash, itching or hives on the skin.

**Do not take this medicine if you have or have had any of the following medical conditions:**

- sudden loss of consciousness sometimes
- asthma, wheezing, difficulty breathing or other severe lung

problems, or have had them in the past

- a history of allergic problems, including hay fever
- a very slow heart beat (less than 45-50 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 heart beat, 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
- swollen ankles and/or tiredness due to heart disease or certain other heart conditions.
- heart failure, heart disorders or 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)
- will be having an operation where certain anaesthetics are used
- respiratory diseases such as asthma
- oculomucocutaneous syndrome (signs include severe conjunctivitis and skin rash and ear infection).

**If you are not sure whether any of the above medical conditions apply to you or whether you should start taking this medicine, talk to your doctor.**

**Do not give this medicine to a child.**

There is not enough information to recommend the use of this medicine for children.

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

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

If it has expired or is damaged, return the pack to your pharmacist for disposal.

*Before you start to take it*

**Tell your doctor if you have allergies to the ingredients in this medicine, any other medicines, foods, preservatives or dyes, bee or wasp stings.**

Your doctor will want to know if you are prone to allergies. Beta-blocker medicines can make allergic reaction worse.

**Tell your doctor if you have or have had any of the following medical conditions:**

- diabetes
- an overactive thyroid gland
- kidney or liver problems
- chest pain when you are resting, or certain types of angina such as Prinzmetal angina or variant angina
- any other heart problems

Your doctor may want to take special precautions if you have any of these conditions.

**Tell your doctor if you are pregnant or plan to become pregnant.**

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

METOPROLOL may affect your baby, especially if you take it in the last few days before your baby is born. Your doctor can discuss with you the risks and benefits involved.

**Tell your doctor if you are breastfeeding or intend to breast-feed.**

Metoprolol passes into breast milk and there is a possibility that your baby could be affected.

**If you have not told your doctor about any of the above, tell him/her before you start taking NOUMED METOPROLOL.**

*Taking other medicines*

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

Some medicines and NOUMED METOPROLOL may interfere with each other. These include:

- other beta-blocker medicines, including beta-blocker eye drops
- other medicines used to treat high blood pressure such as calcium channel blockers or calcium antagonists (e.g. verapamil, diltiazem and nifedipine) and clonidine
- some medicines used to treat angina
- adrenaline or similar substances, which are often found in eye or nose drops, or in cough and cold medicines
- certain medicines used to treat abnormal or irregular heartbeat, for example disopyramide and quinidine
- insulin and tablets used to treat diabetes
- guanethidine, a medicine used to treat certain heart conditions
- certain local or general anaesthetics used during surgery
- monoamine-oxidase inhibitors (MAOIs), used to treat depression
- warfarin, a medicine used to prevent blood clots
- certain medicines, including nonsteroidal anti-inflammatory drugs such as COX-2 inhibitors, used to relieve pain, swelling

and other symptoms of inflammation and arthritis

- cimetidine, used to treat stomach ulcers or reflux
- some antibiotics, such as rifampicin
- some antiviral medicines, such as ritonavir
- some antihistamines, such as diphenhydramine
- some antidepressant medicines, such as paroxetine, fluoxetine, bupropion and sertraline
- some antifungal medicines, such as terbinafine
- ergot alkaloids, a class of medicines used in the prevention and treatment of migraine headaches
- dipyridamole, a medicine used to reduce the risk of blood clots.
- other medicines that may cause a decrease in heart rate (e.g. fingolimod, a medicine used to treat multiple sclerosis)
- other medicines that may cause a decrease in blood pressure (e.g. aldesleukin, a medicine used to treat kidney cancer)

These medicines may be affected by NOUMED METOPROLOL, or may affect how well it works. You may need different amounts of your medicines or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking NOUMED METOPROLOL.

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## How to take NOUMED METOPROLOL

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

They may differ from the information contained in this leaflet.

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

## *How much to take*

### **Hypertension (high blood pressure)**

The usual dosage is 50mg to 100mg either once or twice daily. Your doctor may start you on a low dose and increase it over a period of time.

### **Angina pectoris (chest pain)**

The usual dosage is 50mg to 100mg two to three times daily.

### **After a myocardial infarction (heart attack)**

Your doctor may start you on 50mg twice daily for two days and then continue with 100mg twice daily.

### **Migraine prevention**

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

The daily dosage should not exceed 400mg.

### **Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly how much to take.

### **Follow the instructions they give you.**

If you take the wrong dose, NOUMED METOPROLOL may not work as well and your problem may not improve.

## *How to take it*

### **Swallow the tablets with water or other liquid.**

If you need to break Noumed Metoprolol, hold tablet with both hands and snap along break line.

## *When to take it*

### **Take your medicine at about the same time each day before or after food.**

Taking it at the same time each day will have the best effect. It will also help you remember when to it.

## *How long to take it*

### **Continue taking your medicine for as long as your doctor tells you.**

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

It is important to keep taking your medicine even if you feel well.

## *If you forget to take it*

### **Take your dose as soon as you remember, and continue to take it as you would normally.**

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

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

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

**If you are not sure what to do, ask your doctor or pharmacist.**

**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 the Poisons Information Centre (13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else has taken too much NOUMED METOPROLOL. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention. Keep this telephone number handy.

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) or coma.

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## **While you are taking it**

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### *Things you must do*

### **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 this medicine, tell your doctor immediately.**

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

### **Tell your doctor immediately if you develop a severe allergic reaction to any food, medicine or insect sting while taking NOUMED METOPROLOL.**

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

### **Be careful getting up from a sitting or lying position. Sit and stand up slowly to avoid feeling dizzy or light-headed.**

This will 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.

### **Make sure that you drink enough water during exercise and hot weather when you are taking NOUMED METOPROLOL, especially if you sweat a lot.**

Your blood pressure may drop suddenly if you do not drink enough water while taking NOUMED METOPROLOL.

### **Tell your doctor if you keep feeling dizzy or light-headed.**

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

Noumed Metoprolol may change how well your diabetes is controlled. It may also cover up

some of the symptoms of low blood sugar (hypoglycaemia). Noured Metoprolol may increase the time your body takes to recover from low blood sugar. Your doses of diabetic medicine, including insulin, may need to change.

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking NOUMED METOPROLOL.**

**Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery, tell the surgeon, dentist or anaesthetist that you are taking this medicine.**

Your blood pressure may drop suddenly.

It may also affect other medicines used during surgery.

### *Things you must not do*

**Do not take NOUMED METOPROLOL to treat any other complaints unless your doctor tells you to.**

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

**Do not stop taking NOUMED METOPROLOL, or change the dosage without checking with your doctor.**

By stopping suddenly, your angina may worsen or other heart complications may occur. Your doctor may want you to gradually reduce the amount of NOUMED METOPROLOL you are taking before stopping completely.

### *Things to be careful of*

**Be careful driving or operating machinery until you know how NOUMED METOPROLOL affects you.**

This medicine may cause dizziness, headaches and tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

### **Dress warmly during the cold weather.**

You may feel colder, especially if you will be outside for a long time (for example when playing winter sports). NOUMED

METOPROLOL, like other beta-blocker medicines, may make you more sensitive to cold temperatures, especially if you have circulation problems.

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## Side effects

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NOUMED METOPROLOL.**

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

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

**Do not be alarmed by the following lists of side effects. You may not experience any of them.**

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

- tiredness, drowsiness, decreased alertness
- dizziness, spinning sensation (vertigo), light-headedness or fainting
- headache or other aches and pains
- difficulty sleeping, nightmares
- depression or mood changes
- confusion, short-term memory loss, inability to concentrate
- stomach ache or upset, feeling sick (nausea) or vomiting
- diarrhoea or constipation
- dry or irritated eyes, blurred vision
- buzzing or ringing in the ears, difficulty hearing
- dry mouth, changes in taste sensation

- increased sweating
- runny or blocked nose
- problems with sexual function
- numbness, tingling sensation in the arms or legs
- weight gain
- hair loss or thinning
- worsening of psoriasis
- muscle cramp, painful joints
- weakness, or lack of energy
- troubled sleep, or sleepiness during the day.

Other side effects can also be seen only from blood tests that your doctor will organise from time to time.

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

- signs of allergy such as swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- chest pain, chest tightness, wheezing, rattly breathing
- shortness of breath, sometimes with tiredness and 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 (differs from angina)
- changes in heart rate (fast, slow or irregular) or palpitations
- yellowing of the skin or eyes (jaundice), generally feeling unwell
- 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)
- breathlessness, difficulty breathing when lying down, swelling of the feet or legs, signs of heart disorders.

These side effects could be serious, and you may need urgent medical attention or hospitalisation.

**Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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## After taking it

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### *Storage*

**Keep your medicine in the original container until it is time to take them.**

If you take the tablets out of its original container, they may not keep well.

**Keep your medicine in a cool, dry place, protected from light, where the temperature stays below 25°C.**

Do not store it, or any other medicine, in the bathroom or near a sink. Do not leave it on a windowsill or in the car.

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 its expiry date has passed, ask your pharmacist what to do with any tablets that are left over.

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## Product description

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### *What it looks like*

50 mg: round, white tablets scored on one side. Supplied in blister packs of 100 tablets.

100 mg: round, white tablets scored on one side. Supplied in blister packs of 60 tablets.

### *Ingredients*

#### **Active ingredient**

NOUMED METOPROLOL tablets contain either 50 mg or 100 mg of metoprolol tartrate.

#### **Inactive ingredients**

- lactose monohydrate
- microcrystalline cellulose
- maize starch
- calcium hydrogen phosphate dihydrate
- colloidal anhydrous silica
- crospovidone
- hypromellose
- magnesium stearate.

NOUMED METOPROLOL does not contain sucrose, gluten, tartrazine or any other azo dyes.

### *Sponsor*

Avallon Pharmaceuticals Pty Ltd  
Level 5, 7 Eden Park Drive  
Macquarie Park NSW 2113  
Telephone 1800 930 999

### *Australian Registration number*

50mg: AUST R 298212

100mg: AUST R 298213

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