



**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.

The name of the medicine is Atenolol 5mg/ml Oral Solution but will be referred to as Atenolol throughout this leaflet.

**What is in this leaflet:**

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

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

Atenolol contains the active substance atenolol. This belongs to a group of medicines called beta-blockers. Atenolol is used to:

- ▶ Treat high blood pressure (hypertension).
- ▶ Treat uneven heart beats (arrhythmias).
- ▶ Help prevent chest pain (angina).
- ▶ Protect the heart in the early treatment after a heart attack (myocardial infarction).

It works by making your heart beat more slowly and with less force.

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



**Do not take Atenolol if:**

- ▶ You are allergic to Atenolol or any of the other ingredients of Atenolol (listed in Section 6).
- ▶ You have ever had any of the following heart problems:
  - heart failure which is not under control (this usually makes you breathless and causes your ankles to swell).
  - second- or third-degree heart block (a condition which may be treated by a pacemaker).
  - very slow or very uneven heart beats, very low blood pressure or very poor circulation.

- ▶ You have a tumour called phaeochromocytoma that is not being treated. This is usually near your kidney and can cause high blood pressure. If you are being treated for phaeochromocytoma, your doctor will give you another medicine, called an alpha-blocker, to take as well as Atenolol.
- ▶ You have been told that you have higher than normal levels of acid in your blood (metabolic acidosis).

Do not take Atenolol if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Atenolol.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Atenolol if:

- ▶ **You have asthma, wheezing or any other similar breathing problems, or you get allergic reactions, for example to insect stings. If you have ever had asthma or wheezing, do not take this medicine without first checking with your doctor.**
- ▶ You have a type of chest pain (angina) called Prinzmetal's angina.
- ▶ You have poor blood circulation or controlled heart failure.
- ▶ You have first-degree heart block.
- ▶ You have diabetes. Your medicine may change how you respond to having low blood sugar. You may feel your heart beating faster.
- ▶ You have thyrotoxicosis (a condition caused by an overactive thyroid gland). Your medicine may hide the symptoms of thyrotoxicosis.
- ▶ You have problems with your kidneys. You may need to have some check-ups during your treatment.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Atenolol.



#### Other medicines and Atenolol

Tell your doctor or pharmacist if you are taking, or have recently taken, any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Atenolol can affect the way some other medicines work and some medicines can have an effect on Atenolol.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- ▶ Clonidine (for high blood pressure or migraine). If you are taking clonidine and Atenolol 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.
- ▶ Verapamil, diltiazem and nifedipine (for high blood pressure or chest pain).

- ▶ Disopyramide, quinidine or amiodarone (for an uneven heart beat).
- ▶ Digoxin (for heart problems).
- ▶ Adrenaline, also known as epinephrine (a medicine that stimulates the heart).
- ▶ Ibuprofen or indometacin (for pain and inflammation).
- ▶ Insulin or medicines that you take by mouth for diabetes.
- ▶ Medicines to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy).

#### Operations

If you go into hospital to have an operation, tell the anaesthetist or medical staff that you are taking Atenolol. This is because you can get low blood pressure (hypotension) if you are given certain anaesthetics while you are taking Atenolol.

#### Atenolol with food

Atenolol should not be taken with the food.



#### Pregnancy and breast-feeding

Talk to your doctor before taking Atenolol if you are pregnant, may become pregnant or are breast-feeding.

#### Driving and using machines

- ▶ Your medicine is not likely to affect you being able to drive or use any tools or machines. However, it is best to wait to see how your medicine affects you before trying these activities.
- ▶ If you feel dizzy or tired when taking this medicine, do not drive or use any tools or machines.



#### Atenolol contains:

This medicine contains **methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216)**: May cause allergic reactions (possibly delayed).

#### Sorbitol liquid (non-crystallising)

**(E420)**: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. This medicinal product contains 2.43 mmol (or 55.89 mg) **sodium** per dose (20ml Atenolol). To be taken into consideration by patients on a controlled sodium diet.

### 3. How to take Atenolol

Always take Atenolol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- ▶ Your doctor will tell you how much solution to take each day and when to take it. Read the label on the carton to remind you what the doctor said.
- ▶ Atenolol should be swallowed.
- ▶ Try to take your medicine at the same time each day.

## Adults

- ▶ **High blood pressure (hypertension):** The usual initial dose is 5ml (25mg) per day. The usual maintenance dose is once daily 10 to 20ml (50 to 100mg).
- ▶ **Chest pain (angina):** The usual dose is 10 to 20ml (50 to 100mg) per day. The dose of 20ml (100mg) per day can be divided over two doses per day.
- ▶ **Uneven heart beats (arrhythmias):** the usual dose is 10ml (50mg) to 20ml (100mg) once daily.
- ▶ **The early treatment of a heart attack (myocardial infarction):** the usual dose is 10ml (50mg) to 20ml (100mg) a day.

## Elderly people

If you are an elderly person, your doctor may decide to give you a lower dose, particularly if you have problems with your kidneys.

## People with kidney problems

If you have severe kidney problems your doctor may decide to give you a lower dose.

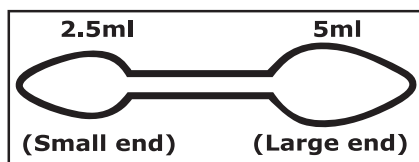
## Children

Your medicine must not be given to children.

## Route and method of administration

This medicinal product must be taken orally.

Use the double ended plastic spoon (as shown below) to measure the required dose. The smaller end measures 2.5ml and larger end measures 5ml.



## If you take more Atenolol than you should

If you take more Atenolol than prescribed by your doctor, talk to a doctor or go to a hospital straight away. Take the medicine pack with you so that the medicine can be identified.

## If you forget to take Atenolol

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

## If you stop taking Atenolol

Do not stop taking Atenolol without talking to your doctor. In some cases, you may need to stop taking it gradually.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### Allergic reactions:

If you have an allergic reaction, see a doctor straight away. The signs may include raised lumps on your skin (weals), or swelling of your face, lips, mouth, tongue or throat.

## See your doctor as soon as possible if you get any of the following side effects:

- ▶ Jaundice (causing yellowing of your skin or the whites of your eyes).
- ▶ You may become more prone to bruising or bleeding or have purplish marks on your skin – this could be a sign of changes to some of the cells or other parts of your blood and your doctor may want to take blood samples every so often to check this.

### Other possible side effects:

**Common** (affects less than 1 in 10 people)

- ▶ You may notice that your pulse rate becomes slower while you are taking the medicine. This is normal, but if you are concerned please tell your doctor about it.
- ▶ Cold hands and feet.
- ▶ Diarrhoea.
- ▶ Feeling sick (nausea).
- ▶ Feeling tired.

**Uncommon** (affects less than 1 in 100 people)

- ▶ Disturbed sleep.

**Rare** (affects less than 1 in 1,000 people)

- ▶ Heart block (which can cause dizziness, abnormal heart beat, tiredness or fainting).
- ▶ Numbness and spasm in your fingers which is followed by warmth and pain (Raynaud's disease).
- ▶ Mood changes.
- ▶ Nightmares.
- ▶ Feeling confused.
- ▶ Changes in personality (psychoses).
- ▶ Hallucinations.
- ▶ Headache.
- ▶ Dizziness (particularly when standing up).
- ▶ Tingling of your hands.
- ▶ Being unable to get an erection (impotence).
- ▶ Dry mouth.
- ▶ Dry eyes.
- ▶ Disturbances of vision.
- ▶ Thinning of your hair.
- ▶ Skin rash.

**Not known** (frequency cannot be estimated from the available data)

- ▶ Lupus-like syndrome (a disease where the immune system produces antibodies that attacks mainly skin and joints).

### Conditions that may get worse

If you have any of the following conditions, they may get worse when you start to take your medicine. This happens rarely affecting less than 1 in 1,000 people.

- ▶ Psoriasis (a skin condition).
- ▶ Being short of breath or having swollen ankles (if you have heart failure).
- ▶ Asthma or breathing problems.
- ▶ Poor circulation.

### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any

possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Atenolol

- ▶ Keep out of the sight and reach of children.
- ▶ Do not use after the expiry date which is stated on the carton or bottle after 'Exp'. The expiry date refers to the last day of that month.
- ▶ Do not store above 25°C.
- ▶ For 100ml and 150ml: Discard 30 days after first opening.
- ▶ For 300ml: Discard 60 days after first opening.
- ▶ Do not throw away any medicine via waste water or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help to protect the environment.

## 6. Contents of the pack and other information

### What Atenolol contains

The active substance is Atenolol.

Each ml of oral solution contains 5mg Atenolol.

The other ingredients are methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), citric acid monohydrate (E330), sodium citrate (E331), sorbitol liquid (non-crystallising) (E420), saccharin sodium (E954), orange flavor [containing propylene glycol (E1520)] and purified water.

### What Atenolol looks like and contents of the pack

Atenolol is clear colourless oral solution with orange flavour supplied in an amber PET bottle with tamper-evident child resistant plastic cap and a double-ended plastic spoon for measuring and administering the dose.

Atenolol is supplied in bottles containing 100ml, 150ml and 300ml solution.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder:

Syri Pharma Limited t/a  
Thame Laboratories  
Floor 0, 1 WML,  
1 Windmill Lane,  
Dublin 2, D02 F206, Ireland.

**POM**

### Manufacturer:

Syri Limited t/a Thame Laboratories  
Unit 4, Bradfield Road,  
Ruislip, Middlesex,  
HA4 0NU, UK

This leaflet was last revised in 01/2020.





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It works by making your heart beat more slowly and with less force.

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



#### Do not take Atenolol if:

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- ▶ You have ever had any of the following heart problems:
  - heart failure which is not under control (this usually makes you breathless and causes your ankles to swell).
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- ▶ Atenolol should be swallowed.
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## Adults

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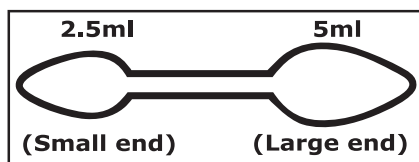
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## Route and method of administration

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If you forget to take a dose, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

## If you stop taking Atenolol

Do not stop taking Atenolol without talking to your doctor. In some cases, you may need to stop taking it gradually.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

### Allergic reactions:

If you have an allergic reaction, see a doctor straight away. The signs may include raised lumps on your skin (weals), or swelling of your face, lips, mouth, tongue or throat.

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### Other possible side effects:

**Common** (affects less than 1 in 10 people)

- ▶ You may notice that your pulse rate becomes slower while you are taking the medicine. This is normal, but if you are concerned please tell your doctor about it.
- ▶ Cold hands and feet.
- ▶ Diarrhoea.
- ▶ Feeling sick (nausea).
- ▶ Feeling tired.

**Uncommon** (affects less than 1 in 100 people)

- ▶ Disturbed sleep.

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- ▶ Heart block (which can cause dizziness, abnormal heart beat, tiredness or fainting).
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**Not known** (frequency cannot be estimated from the available data)

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## 5. How to store Atenolol

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**POM**

### Manufacturer:

Pharmadox Healthcare Ltd.,  
KW20A Kordin Industrial Park,  
Paola PLA3000, Malta.

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