

## Package leaflet: Information for the patient

**Atenolol Sandoz<sup>®</sup> 25, tabletten 25 mg**  
**Atenolol Sandoz<sup>®</sup> 50, tabletten 50 mg**  
**Atenolol Sandoz<sup>®</sup> 100, tabletten 100 mg**

**atenolol**

**Read all of this leaflet carefully before you start using 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.

### What is in this leaflet

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

#### 1. What [Nationally completed name] is and what it is used for

[Nationally completed name] contains a medicine called atenolol. This belongs to a group of medicines called beta-blockers.

[Nationally completed name] is used to:

- treat high blood pressure (hypertension)
- treat chest pain caused by “chronic stable angina pectoris”
- treat some types of uneven heart beats (arrhythmias)
- help prevent another heart attack from happening.

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

#### 2. What you need to know before you take [Nationally completed name]

**Do not take [Nationally completed name] if:**

- You are allergic to atenolol or any of the other ingredients of this medicine (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 (less than 45-50 beats per minute) or very uneven heart beats, very low blood pressure or very poor circulation.
- you have cardiogenic shock. This is when your heart does not pump your blood around your body well enough. Signs may include confusion, sweating, a fast heartbeat and pale skin.
- 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 [Nationally completed name]. Blood pressure levels should be monitored closely.
- You have been told that you have higher than normal levels of acid in your blood (metabolic acidosis).
- You have severe asthma, with wheezing and difficult breathing.

Tell your doctor that you are taking [Nationally completed name]. If you take [Nationally completed name], certain medicines for irregular heartbeat (such as disopyramide or calcium antagonists of the verapamil or diltiazem type) should not be administered intravenously.

Do not take [Nationally completed name] if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking [Nationally completed name] 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 not feel your heart beating faster or stronger. Blood sugar levels should be monitored closely.
- 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.
- You have a skin problem called psoriasis.
- You have a slow heartbeat (50 to 55 beats per minute).
- You have a tumour called "phaeochromocytoma" you should also be treated with medicines called alpha blockers in addition to [Nationally completed name]. Blood pressure should be monitored closely.
- You are an elderly person.
- you have poor blood flow to the heart muscle (ischaemic heart disease). Treatment with [Nationally completed name] should not be discontinued suddenly.

If any of the above applies to you (or you are not sure), talk to your doctor or pharmacist before taking this medicine.

With other medicines from the same group (beta-blockers), in very rare cases, worsening of renal function or damage to the liver can occur. Your kidney and liver function should therefore be checked regularly.

Taking atenolol can lead to disorders in lipid metabolism. A decrease in ‘good’ cholesterol (HDL cholesterol) and an increase in blood triglycerides have been observed.

### **Other medicines and [Nationally completed name]**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription such as herbal medicines. This is because [Nationally completed name] can affect the way some other medicines work. Also some other medicines can affect the way [Nationally completed name] works.

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

- Clonidine (for high blood pressure or migraine). If you are taking clonidine and [Nationally completed name] 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 heartbeat).
- 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.
- Ampicillin, for bacterial infections.
- Barbiturates, for sleeping problems and epilepsy.
- Sultopride and phenothiazines, for more serious mental health problems (psychoses).
- Medicines for depression from the groups called “tricyclic anti-depressants” or “MAO-inhibitors”
- Medicines to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy).
- Medicines used to reduce pressure in the eye caused by glaucoma or other eye conditions.
- Muscle relaxants (e.g. tubocurarine chloride, medicines for relaxing muscles that are used in operations).
- Baclofen (for spastic movement disorders).
- Certain medicines for high blood pressure (reserpine, alpha-methyldopa, guanfacine).

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking this medicine.

### **Operations**

If you go into hospital to have an operation, tell the anaesthetist or medical staff that you are taking [Nationally completed name]. This is because you can get low blood pressure (hypotension) if you are given certain anaesthetics, or substances containing iodine (called a “contrast media”) for X-rays, while you are taking [Nationally completed name].

### **Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Atenolol is not recommended during pregnancy or 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.

Caution is recommended especially at the start of treatment, dose increase, and in combination with alcohol.

#### **[Nationally completed name] contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

### **3. How to take [Nationally completed name]**

Always take [Nationally completed name] 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 many tablets to take each day and when to take them.
- Read the label on the carton to remind you what the doctor said.
- Try to take your tablets at the same time each day.
- Swallow the tablets in whole with a drink of water before the meals. The score line is only there to help you to break the tablet if you have difficulty swallowing it whole.

#### **Adults**

Your doctor will decide how much [Nationally completed name] you should take each day, depending on your condition.

##### **High blood pressure**

- The usual starting dose is 25 mg once daily.
- You will then usually take between 50 mg and 100 mg once daily.

##### **Chest pain**

The usual dose is between 50 mg and 100 mg once daily. If you are taking 100 mg, your doctor may ask you to take this as two separate doses, 50 mg in the morning and 50 mg in the evening.

##### **Uneven heart beats**

The usual dose is between 50 mg and 100 mg once daily.

##### **To help prevent another heart attack**

The usual dose is 100 mg once daily. Your doctor may ask you to take this as two separate doses, 50 mg in the morning and 50 mg in the evening.

#### **Elderly**

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 severe kidney problems**

If you have severe problems with your kidneys, your doctor may give you a lower dose of [Nationally completed name] or tell you to take it less often.

#### **Use in children**

Your medicine must not be given to children.

#### **If you take more [Nationally completed name] than you should**

- If you take more [Nationally completed name] than you should, talk to a doctor or go to a hospital straight away.
- Take the medicine pack with you so that the doctor knows what you have taken.
- You may get a slow heartbeat, feel dizzy due to low blood pressure, have difficulty breathing, feel sick, have decreased consciousness and suffer generalized seizures. Your heart may also have trouble supplying blood to the rest of your body (acute heart failure).

#### **If you forget to take [Nationally completed name]**

- 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 [Nationally completed name]**

Do not stop taking [Nationally completed name] without talking to your doctor. The doctor may need to slowly lower the dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. Do not be concerned by this list of side effects. You may not get any of them. The following side effects may happen with this medicine:

**Stop taking [Nationally completed name] and see a doctor or go to hospital straight away if you notice any of the following serious side effects:**

#### **Rare: may affect up to 1 in 1,000 people**

- an abnormal heart beat, feeling dizzy, tired or fainting. These could be signs of heart block.
- shortness of breath or having swollen ankles. These could be signs of heart failure or your heart failure getting worse.
- breathing problems such as wheezing. These could be signs of your asthma getting worse.

#### **Very rare: may affect up to 1 in 10,000 people**

- swelling of your face or throat, difficulty in breathing or feeling dizzy. These may be signs of a serious allergic reaction.

Stop taking [Nationally completed name] and see a doctor or go to hospital straight away if you notice any of the side effects above.

**Other side effects include:**

**Common: may affect up to 1 in 10 people**

- cold or poor blood circulation in your hands and feet
- your pulse rate may become slower. This is normal, but if you are worried tell your doctor about it.
- diarrhoea
- constipation
- feeling sick or being sick
- feeling tired
- feeling faint
- sweating.

**Uncommon: may affect up to 1 in 100 people**

- problems sleeping
- discharge from the eye with itching, redness and swelling
- muscle weakness
- muscle cramps
- worsening of existing diabetes mellitus (high level of sugar in the blood)
- high levels of an enzyme called “transaminase” (shown by blood tests).

**Rare: may affect up to 1 in 1,000 people**

- purple skin patches
- tingling or pins and needles of your hands and feet
- poor circulation (“Claudicatio intermittens”) that may get worse when you first start taking this medicine
- low blood pressure which may cause dizziness, light-headedness or fainting
- headache
- feeling dizzy
- feeling confused, anxious or scared
- nightmares
- changes in personality (psychoses) or seeing or hearing things that are not there (hallucinations)
- depression
- mood changes
- dry mouth
- thinning of your hair
- dry eyes
- rash
- dry scaly skin (psoriasis) that may get worse when you start to take your medicine
- problems with your eye-sight
- hair loss
- bruising more easily or purple marks on your skin
- unable to get an erection in men (impotence)
- change in sex drive
- yellowing of your skin or the whites of your eyes (jaundice)

- blood problems such as changes to your blood cells. Your doctor may take blood samples every so often to check whether [Nationally completed name] has had any effect on your blood.

**Very rare: may affect up to 1 in 10,000 people**

- more intense seizures in patients with chest pain (angina pectoris)
- Changes to some of the cells or other parts of your blood. Your doctor may take blood samples every so often to check whether [Nationally completed name] has had any effect on your blood.

**Not known: frequency cannot be estimated from the available data**

- allergic (hypersensitivity) reactions such as itchy rash
- [Nationally completed name] may hide the symptoms of "thyrotoxicosis" and low blood sugar levels (diabetes) (see "Section 2. What you need to know before you take [Nationally completed name]")
- disorders of central nervous system, particularly at the start of treatment
- lupus-like syndrome (a disease where the immune system produces antibodies that attacks mainly skin and joints).

**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 [the national reporting system](#) listed in Appendix V\*. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store [Nationally completed name]**

Keep out of the sight and reach of children.

Do not use [Nationally completed name] after the expiry date which is stated on the carton and blister after 'EXP'. The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original container in order to protect from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. Contents of the pack and other information**

**What [Nationally completed name] contains**

- The active substance is atenolol. Each tablet contains 25 mg of atenolol.  
Each tablet contains 50 mg of atenolol.  
Each tablet contains 100 mg of atenolol.
- The other ingredients are povidone K25, maize starch, microcrystalline cellulose, sodium starch glycolate, magnesium stearate and colloidal anhydrous silica.

**What [Nationally completed name] looks like and contents of the pack**  
*25 mg tablets:*

White, round biconvex tablets, on one side marked with '25', and on the other side a score.  
Diameter: 7 mm

*50 mg tablets:*

White, round biconvex tablets, on one side marked with '50', and on the other side a score.  
Diameter: 8 mm

*100 mg tablets:*

White, round biconvex tablets, on one side marked with '100' and on the other side a score.  
Diameter: 10 mm

The tablets are packed in aluminium/PVC blisters and inserted in a carton.

*25 mg tablets:*

Pack sizes:

B blister: 28, 30, 56, 100, 100x1 and 250 tablets

*50 mg tablets:*

Pack sizes:

B blister: 14, 20, 28, 30, 50, 56, 60, 98, 100, 100x1, 300 and 500 tablets

*100 mg tablets:*

Pack sizes:

B blister: 14, 20, 21, 28, 30, 42, 50, 56, 60, 98, 100, 100x1, 300 and 500 tablets

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Houder van de vergunning voor het in de handel brengen**

Sandoz B.V., Veluwezoom 22, 1327 AH Almere, Nederland

#### **Fabrikanten**

Salutas Pharma GmbH  
Otto-von-Guericke Allee 1  
39179 Barleben  
Duitsland

LEK Pharmaceuticals d.d  
Verovškova 57  
1526 Ljubljana  
Slovenië

#### **In het register ingeschreven onder:**

Atenolol Sandoz 25 is in het register ingeschreven onder RVG 24399.

Atenolol Sandoz 50 is in het register ingeschreven onder RVG 14705.

Atenolol Sandoz 100 is in het register ingeschreven onder RVG 14706.

**This medicinal product is authorised in the Member States of the EEA under the following names:**



Belgium:	Atenolol Sandoz 25 mg, tabletten Atenolol Sandoz 50 mg tabletten Atenolol Sandoz 100 mg, tabletten
Denmark:	Atenolol "Sandoz"
Finland:	Atenolol Sandoz 25 mg tabletit Atenolol Sandoz 50 mg tabletit
The Netherlands:	ATENOLOL SANDOZ 25, tabletten 25 mg ATENOLOL SANDOZ 50, tabletten 50 mg ATENOLOL SANDOZ 100, tabletten 100 mg
Sweden:	Atenolol Sandoz 25 mg tabletter Atenolol Sandoz 50 mg tabletter Atenolol Sandoz 100 mg tabletter

**Deze bijsluiter is voor het laatst goedgekeurd in maart 2021**