

Package leaflet: Information for the user

atenolol cinfa 50 mg tablets

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.

What is in this leaflet

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

1. What atenolol cinfa is and what it is used for

atenolol cinfa belongs to a group of medicines called beta-blockers, in other words, it acts on your heart and circulatory system.

This medication is used to treat arterial hypertension, chest pain, cardiac arrhythmias (to secure a regular and adequate heart beat) and acute myocardial infarction (to protect the heart during and after infarction).

2. What you need to know before you take atenolol cinfa

Do not take atenolol cinfa:

- If you are allergic (hypersensitive) to atenolol or any of the other ingredients of this medicine (included in section 6).
- If you have or have had heart disease such as heart block or uncontrolled heart failure, or sick sinus syndrome.
If you have metabolic acidosis (a metabolic disorder that it causes excessive blood acidity).
- If you have a very slow or irregular heartbeat, if your blood pressure is very low or you have circulatory problems (circulatory failure).
- If you have been told you have a phaeochromocytoma (a tumour of the adrenal glands).
- If you are fasting.

In any case, consult your doctor. Atenolol is contraindicated in children.

This medicine, atenolol cinfa, has been specifically prescribed by your doctor for you. Therefore, do not pass it on to others.

Warnings and precautions

Talk to your doctor or pharmacist before taking atenolol cinfa.

Before starting treatment with atenolol, inform your doctor:

- If you have any illness, especially asthma or breathing difficulties, diabetes, circulatory problems, Prinzmetal angina, phaeochromocytoma or diseases of the heart, kidneys or thyroid gland.
- If you are pregnant or think you may be, or if you are breast feeding (see the section on Pregnancy and Breast-feeding).
- If you have experienced any allergic problems, for example, to an insect bite.
- If you are taking any other medicine (see the section on Interactions).

If you are programmed for surgery, inform the anaesthetist that you are taking this medication.

It is normal to notice a slowed pulse during treatment. If you are not sure about the importance of this condition, please consult your doctor.

If you have diabetes, you must take into account that this medication can counter one of the first symptoms that help you to identify a hypoglycaemic episode: tachycardia.

Only suspend the medication if your doctor tells you to do so. In any case, treatment should never be suspended suddenly but gradually.

Children

The safety of atenolol in children has not been established. This medicine therefore should not be used in children.

Other medicines and atenolol cinfa

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those acquired without medical prescription, such as homoeopathic products, herbal remedies, and other health products, as it may be necessary to stop treatment or adjust the dose of some of them. Some drugs may affect how other drugs work.

This is particularly important in the case of:

- Antiarrhythmics: disopyramide or amiodarone.
- Medicines used for arterial hypertension or angina pectoris (verapamil, diltiazem, nifedipine, clonidine). If you are taking clonidine for arterial hypertension or for the prevention of migraine, do not suspend treatment with either clonidine or atenolol without first consulting your doctor.
- Medicines used for heart failure (digoxin).
- Antiinflammatory medicines for treatment of pain such as indomethacin or ibuprofen.
- Any nasal decongestant or medicine for the common cold.
- Anaesthetics

Check with your doctor or pharmacist if you are not sure.

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.

Pregnancy

Tell your doctor if you are pregnant, if you are planning to have a baby or are breast-feeding.

There is insufficient data on the safety of atenolol cinfa during the first trimester of pregnancy. Your doctor will decide if treatment during the second and third trimester is beneficial for you.

Breast-feeding

Tell your doctor if you are being treated with atenolol cinfa, at the moment of birth or during breast-feeding, as your baby may be at risk of low blood sugar and a slower heartbeat.

Atenolol enters breast milk.

Use in elderly patients

Dose reduction may prove necessary, especially if kidney function is altered.

Use in patients with impaired renal function:

Dose reduction may prove necessary, but this must be decided by your doctor (see section 3).

Driving and using machines

It is unlikely for treatment with atenolol to have a negative effect on the ability to drive and use machines, but these activities may be affected by adverse reactions to the medication, such as dizziness or tiredness. In such cases, driving and the use of machines should be avoided.

Use in athletes

This medicinal product contains atenolol, which can produce a positive anti-doping test result.

atenolol cinfa contains sodium.

This medicine contains less than 1 mmol of sodium (23 mg) per dose unit; that is, it is essentially “sodium-free”.

3. How to take atenolol cinfa

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is 50-100 mg a day (1 or 2 tablets of atenolol cinfa 50 mg).

This medicine is usually taken once a day, though the daily dose can also be divided into two fractions.

- atenolol cinfa tablets are to be swallowed whole with the help of a little water.
- Try to take the tablets at the same time each day.
- Remember to take your medicine. Your doctor will indicate to you the duration of your treatment with atenolol cinfa.
- It is very important to continue taking atenolol cinfa as long as instructed by your doctor.
- The tablet can be divided into equal doses. Do not stop taking your tablets even though you feel well, at least until your doctor tells you to do so. In this case, you must do so gradually.

Adults

High blood pressure: the starting dose is 50 mg daily. The maximum effect will occur after 1-2 weeks of treatment. If the response is not sufficient, the dose can be increased up to 100 mg. Exceeding this does not usually increase its efficacy. An additional reduction in blood pressure can be achieved by combining atenolol cinfa with other antihypertensive drugs.

Chest pain (angina): although treatment usually also begins with a dose of 50 mg per day, the effective dose is generally 100 mg in a single oral dose or in two doses of 50 mg per day.

Irregular heartbeat: after controlling the arrhythmias with intravenous treatment, the appropriate oral maintenance dose is 50-100 mg/day, administered as a single dose.

Early protection after a heart attack: in patients in which β -blocker treatment is indicated, therapy should start via the intravenous route, followed by oral administration in the form of 50 or 100 mg/day. If bradycardia and/or hypotension occur requiring treatment, or if any other undesirable effect occurs, this treatment must be suspended.

Late protection after a heart attack: if several days have passed since the acute myocardial infarction, as a long-term prophylaxis, an oral dose of Atenolol of 100 mg/day is recommended.

Patients with renal failure:

If you have severe kidney problems, your doctor may prescribe a lower dose of atenolol or tell you to take it less frequently.

Given that Atenolol is eliminated via the kidneys, the dose must be reduced in cases of severe renal impairment. If creatinine clearance is:

- Over 35 ml/min/1.73 m² (the normal range is 100-150 ml/min/1.73 m²) no dose adjustment is required.
- 15-35 ml/min/1.73 m² (equivalent to a serum creatinine value of 300-600 μmol/l), the maximum oral dose is 50 mg/day.
- <15 ml/min/1.73 m² (equivalent to a serum creatinine value of >600 μmol/l), the maximum oral dose is 50 mg on alternate days, or 100 mg every 4 days.

Patients undergoing haemodialysis will receive 50 mg of Atenolol orally after of every dialysis session.

The medicinal product must be administered in a hospital environment, as it can cause sharp drops in blood pressure.

If you take more atenolol than you should

The symptoms of overdose can include bradycardia, hypotension, sinus block, acute heart failure, hypoglycaemia and bronchospasm.

In case of overdose or accidental ingestion, tell your doctor or pharmacist immediately.

If you forget to take atenolol

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten 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.

Common (may affect up to 1 out of every 10 people):

- Cold fingers and toes.
- Slowed heart rate.
- Gastrointestinal disorders (nausea and diarrhoea).
- Fatigue.

Uncommon (may affect up to 1 in 100 people):

- Sleep disorders, similar to those that occur with other beta-blockers.

Rare (may affect up to 1 out of every 1000 people):

- Heart block (which can cause an abnormal heartbeat, light-headedness, tiredness or fainting).
- Worsening of breathing problems if you have or have had asthma.
- Insufficient respiration and/or inflammation of the ankles, if you also suffer from heart failure.
- Worsening of your arterial circulation, if you already suffer from some degree of circulatory insufficiency.
- Numbness and spasms in the fingers, followed by a sensation of heat and pain ("Raynaud's phenomenon").
- Mood swings.

- Nightmares.
- Confusion.
- Psychosis or hallucinations (mental disorders).
- Headache.
- Dizziness, specially when standing up.
- Tingling sensation in the hands.
- Impotence.
- Dry mouth.
- Dry eyes.
- Visual disorders.
- Hair loss.
- Skin rash, including worsening of psoriasis.
- Thrombocytopenia (bruising more easily).
- Purpura (purple spots on the skin).
- Jaundice (yellow colouration of the skin and/or eyes).

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

Very rarely there may be changes to some cells or components of the blood. Your doctor might wish to perform a blood test to check if atenolol cinfa has had any effect on your blood.

Unknown frequency (cannot be estimated from the available data):

Syndrome similar to lupus (a disease in which the immune system produces antibodies that mainly attack the skin and joints).

Do not be alarmed by this list of side effects, as it is possible that none of them will appear in your case.

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.

5. How to store atenolol cinfa

Do not store at a temperature above 25°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the container after “EXP”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What atenolol cinfa contains

- The active substance is atenolol. Each tablet contains 50 mg of atenolol.
- The other ingredients are: magnesium carbonate, gelatine, maize starch, sodium lauryl sulphate and magnesium stearate.

Contents of the pack

Atenolol cinfa 50mg tablets come in packs of 30 tablets.

Marketing Authorisation Holder and Manufacturer

Laboratorios Cinfa, SA
C/Olaz-Chipi, 10 - Polígono Industrial Areta
31620, Huarte, Pamplona, Navarre, Spain

Distributor

Reich Pharm Limited
Unit 3001, 30/F, Citicorp Centre,
18 Whitfield Road,
Hong Kong
Tel.: 2470 1927
Fax.: 2470 3448

HK Reg. No. 52982

This leaflet was last reviewed in November 2018

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- If you are taking any other medicine (see the section on Interactions).

If you are programmed for surgery, inform the anaesthetist that you are taking this medication.

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- Insufficient respiration and/or inflammation of the ankles, if you also suffer from heart failure.
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C/Olaz-Chipi, 10 - Polígono Industrial Areta
31620, Huarte, Pamplona, Navarre, Spain

Distributor

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HK Reg. No. 52981

This leaflet was last revised in November 2018