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, which means that it acts on your heart and circulatory system.

atenolol cinfa is indicated in the treatment of high blood pressure (hypertension), to help prevent chest pain (angina), to ensure a regular heartbeat and also to protect the heart during and after a heart attack.

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

not take atenolol cinfa

- if you are allergic to atenolol or to any of the other ingredients of this medicine (listed in section 6).
- If you have had or are suffering from heart conditions such as uncontrolled heart failure.
- If you have other heart conditions:
 - second- or third-degree heart block (a condition that can be treated with a pacemaker)
 - bradycardia (very slow or very irregular heartbeat)
 - very low blood pressure (hypotension)
 - due to circulation (peripheral arterial disease)
 - or circulatory failure.
- If you have a tumour called pheochromocytoma (a tumour in the adrenal glands).
- If you have been fasting.
- If you have been told that you have metabolic acidosis (a metabolic disorder that causes excessive acidity of the blood) that is not being treated. It is usually near the kidney and can cause high blood pressure.
- If you have been fasting.
- If you have been told that you have higher than normal levels of acid in your blood (metabolic acidosis).
- Atenolol must not be administered to children.

This medicine has been specifically prescribed for you by your doctor. Therefore, you should not give it to anyone else.

Warnings and precautions

Talk to your doctor or pharmacist before taking atenolol cinfa.

- If you have health problems such as asthma or breathing problems, diabetes, circulatory disorders, heart, kidney or thyroid problems.
- If you have ever been told that you suffer from a special type of chest pain (angina), called Prinzmetal's angina.
- If you are pregnant, if you are planning to have a baby or are breast-feeding. See "Pregnancy and breast-feeding" section.
- If you have ever had an allergic reaction to something, e.g. an insect bite.
- You may notice that your pulse slows down while taking these tablets. This is normal, but if it concerns you, tell your doctor.
- If you are diabetic, atenolol may change your normal response to low blood glucose, which usually means an increase in heart rate.
- If you are admitted to hospital, tell the healthcare staff, especially the anaesthetist, that you are being treated with atenolol.
- Only stop taking your tablets if your doctor tells you to do so, and then only gradually.

Children

The safety of atenolol in children has not been established, and therefore it 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. This includes non-prescription medicines, homeopathic medicines, herbal medicines and other health-related products, as it may be necessary to interrupt the treatment or adjust the dose of some of them. Some medicines may affect the action of others, in particular, tell your doctor if you are using:

- Disopyramide or amiodarone (for irregular heartbeat).
- Other treatments for hypertension or angina (in particular verapamil, diltiazem, nifedipine, clonidine). If you are using clonidine for high blood pressure or to prevent migraine, do not stop taking it or atenolol without first consulting your doctor.
- Treatment for heart failure (digoxin).
- Anti-inflammatory medicines for treatment of pain (such as indomethacin or ibuprofen).
- Nasal decongestants or other cold products that you may have bought yourself in a pharmacy.

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

There is insufficient data on the safety of atenolol 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, at the time of birth or during breast-feeding, as your baby may be at risk of low blood sugar and a slower heartbeat.

Breast-feeding women should consult their doctor before taking this medicine as atenolol passes into breast milk.

Driving and using machines

Observe your response to medication because in some cases dizziness and fatigue have occurred at the usual

doses. If this happens, do not drive or operate dangerous machinery.

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 (23 mg) of sodium per tablet, i.e. 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 per day.

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

- Atenolol tablets should be swallowed whole with a little water.
- The tablet can be divided into equal doses.
- Try to take the tablets at the same time each day.
- Remember to take your medicine. Your doctor will tell you the duration of your treatment with atenolol.
- It is very important to continue taking this medicine for the time recommended by the doctor.
- Do not stop taking this medicine even if you feel well, unless your doctor tells you to do so; in this case, you should do so gradually.

Adults

- **High blood pressure (hypertension):** the recommended dose is 50 to 100 mg per day.
- Chest pain (angina): the recommended dose is 100 mg daily or 50 mg twice daily.
- Irregular heartbeat (arrhythmias): the recommended dose is 50 mg to 100 mg per day.
- Early treatment of a heart attack (myocardial infarction): the recommended dose is 50 mg to 100 mg per day.
- Later treatment of a heart attack (myocardial infarction): the recommended dose is 100 mg per day.

Patients with renal failure:

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

If you take more atenolol cinfa than you should

If you take more than the normal dose, contact your doctor or nearest hospital.

In case of overdose or accidental ingestion, consult your doctor or pharmacist immediately indicating the medicine and quantity ingested.

If you forget to take atenolol cinfa

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 in 10 people):

- Cold fingers and toes.
- Slower heartbeat.
- Nausea.
- Diarrhoea.
- Fatigue.

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

- Disturbed sleep.

Rare (may affect up to 1 in 1,000 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.
- Shortness of breath and/or swelling of the ankles if you also have heart failure.
- Worsening of your arterial circulation if you already suffer from some degree of circulatory failure.
- 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, especially 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 (which can be detected as a yellowing of your skin and eyes).
- Elevated serum enzyme values (transaminases).

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 had any effect on your blood.

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

Lupus-like syndrome (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. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store atenolol cinfa

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

Do not store at temperatures above 25°C.

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.

What atenolol cinfa looks like and contents of the pack

White, round, biconvex tablets, scored on one side, and with the inscription A50C on the other. It is supplied in PVC/ALU blisters. Each pack contains 30 tablets.

Marketing Authorisation Holder and Manufacturer

Laboratorios Cinfa, S.A. Carretera Olaz-Chipi, 10. Polígono Industrial Areta, 31620, Huarte (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 revised in: July 2021

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