



Package leaflet:
Information for the user

Acebutolol 400 mg film-coated tablets

acebutolol hydrochloride

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 Acebutolol is and what it is used for
2. What you need to know before you take Acebutolol
3. How to take Acebutolol
4. Possible side effects
5. How to store Acebutolol
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1. What Acebutolol is and what it is used for

The name of your medicine is Acebutolol 400 mg Tablets. This belongs to a group of medicines called beta-blockers. It works by slowing your heart rate or lowering your blood pressure.

Acebutolol is used for:

- Chest pain (angina)
- High blood pressure
- Uneven or unusually fast heart beats (arrhythmia)

2. What you need to know before you take Acebutolol

Do not take this medicine if:

- You are allergic (hypersensitive) to acebutolol hydrochloride, other betablockers or any of the other ingredients of Acebutolol (see Section 6: Further information) Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have low blood pressure
- You have severe heart problems or heart failure not controlled by medicines
- You have a very slow heartbeat - less than 50 beats per minute
- Your doctor has told you that you have an abnormal level of acid in your blood (called acidosis).
- You have serious blood circulation problems
- You have a tumour on the adrenal gland (called pheochromocytoma)
- You are taking floctafenine (used to treat pain), or sultopride (used to treat certain mental illnesses)
- You are breast-feeding
- You have asthma or chronic obstructive pulmonary disease in their severe forms".

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Acebutolol

You should never suddenly stop your treatment without first asking your doctor's advice because a sudden stop can put your life in danger.

You should also tell your doctor:

- If you have kidney problems
- If you have heart failure that is controlled with medicines
- If you have a slow heart beat (also see section 'Do not take Acebutolol if')
- If you have breathing problems due to long term lung problems (called 'asthma', 'bronchitis' or 'emphysema')
- If you have an overactive thyroid gland
- If you have diabetes or low blood sugar levels (hypoglycaemia)
- If you have psoriasis
- If you have mild or moderate blood circulation problems. You may have cold hands and feet that look darker than the rest of your body
- If you have a form of chest pain known as 'Prinzmetal's' angina
- If you have a history of allergies

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

Operations or anaesthetics

Tell your doctor or dentist you are taking Acebutolol if you are going to have an anaesthetic or an operation (including dental surgery).

Other medicines and Acebutolol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. An increased risk of depression has been reported when co-administered with diltiazem.

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

- Other medicines for high blood pressure
- Clonidine used for migraine or high blood pressure. If you are taking clonidine and Acebutolol together, you should not stop taking clonidine unless your doctor tells you. If you have to stop taking clonidine, your doctor will give you instructions
- Medicines for chest pain (angina) such as verapamil, nifedipine or diltiazem. Verapamil must not be taken within several days of taking Acebutolol
- Medicines for heart problems such as amiodarone, disopyramide or digoxin
- Medicines used for mental health problems (antipsychotic medicines) - such as haloperidol, sulphiride, pimozide, flupenthixol or sultopride
- Some medicines used for depression (mono-amine oxidase inhibitors or tricyclic antidepressants) such as phenelzine, imipramine or amitriptyline
- Medicines to help you sleep (barbiturates) such as amobarbital
- Insulin or tablets to treat diabetes - such as glibenclamide. Your doctor may change your dose.
- Lidocaine used by IV (a medicine used in anaesthesia)
- Medicines likely to give torsades de pointes (serious heart rhythm disorder)
- Medicines that can cause a drop in blood pressure when going from lying down to standing up (orthostatic hypotension)
- Dapoxetine (medicine used in ejaculation disorders in men)
- IV dipyridamole (medicine used to prevent thromboembolic accidents)
- Medicines used for breathing problems -such as aminophylline, theophylline, salbutamol and terbutaline
- Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) - used to relieve pain (such as ibuprofen, naproxen, diclofenac, indometacin, piroxicam and floctafenine)
- Fingolimod used for treating multiple sclerosis. Your doctor may perform monitoring at the start of treatment
- Pilocarpine (medicine used as eye drops in the treatment of glaucoma or as a tablet in the treatment of certain cases of dry mouth)
- Baclofen (used to treat muscle stiffness) because it can cause a more pronounced reduction in blood pressure. Blood pressure should be monitored more frequently and the antihypertensive dose reduced if necessary.
- Iodine X-ray contrast agents because they can cause shock and low blood pressure; beta blockers reduce the heart's ability to respond to these reactions. Non-steroidal anti-inflammatory drugs (anti-inflammatory drugs) as they may reduce the ability of Acebutolol to lower blood pressure.
- Corticosteroids (anti-inflammatory medicines), tetracosactide (a medicine used in endocrinology) because they may reduce the blood pressure lowering effect of Acebutolol.
- Mefloquine (used to treat malaria) as it can cause a reduction in heart rate.

Acebutolol with food, drink and alcohol

Take Acebutolol with or just after meals

Pregnancy, breast-feeding and fertility

Talk to your doctor before taking this medicine if:

- You are pregnant, might become pregnant, or think you may be pregnant. Acebutolol should not normally be given during pregnancy as it may cause problems with the foetus or newly born baby.
- You are breast-feeding or planning to breast-feed. You should not breastfeed if you are taking Acebutolol. This is because small amounts may pass into mothers' milk. Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.
- Beta-blockers can reduce blood flow to the placenta, which can result in premature birth, newborn smaller than expected, intrauterine foetal death and abortion.

Driving and using machines

You may feel tired or dizzy while taking this medicine. If this happens, do not drive or use any tools or machines.

Acebutolol Tablets contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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Version: 03

Date & Time: 12.12.2023 & 4.50 pm

Submission Code: N18928_u15c

P15xxxxx

3. How to take Acebutolol

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

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets with a drink of water
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor

How much to take

Adults (including the elderly)

The usual dose of Acebutolol depends on your needs and the illness being treated. Your doctor will advise you.

Chest pains (angina)

- The starting dose is 400 mg once a day at breakfast or 200 mg twice a day
- If necessary, your doctor may increase this to 300 mg three times a day
- The maximum daily dose is 1200 mg

High blood pressure

- The starting dose is 400 mg once a day at breakfast or 200 mg twice a day
- If necessary, after 2 weeks, your doctor may increase this to 400 mg twice a day

Uneven or unusually fast heart beats (arrhythmia)

- The starting dose is 200 mg daily
- If necessary, your doctor may increase this to 400 mg to 1200 mg daily

Patients with kidney problems

Your doctor may decide to lower your dose of Acebutolol if necessary.

If you take more Acebutolol than you should

- Tell a doctor or go to a hospital casualty department straight away.
- Take the medicine pack with you. This is so the doctors know what you have taken.
- The following effects may happen:
Feeling dizzy or weak, difficulty in breathing or wheezing, low blood sugar or serious heart problems.

If you forget to take Acebutolol

If you forget a dose, take it as soon as you remember it. However, if it is nearly 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 Acebutolol

Keep taking Acebutolol until your doctor tells you to stop. If you stop treatment suddenly your illness may get worse. When your doctor says that you can stop taking Acebutolol, you need to do this gradually. Your doctor will help you do this.

If you have any further questions about 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.

Stop taking Acebutolol and see your doctor or go to a hospital straight away if:

- You have an allergic reaction. The signs may include: rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Tell your doctor as soon as possible if you have any of the following side-effects:

Very common (affects more than 1 person in 10)

- Blood tests may show changes to your immune system. Signs may include joint aches and pains, swollen joints, increased sensitivity to sunlight, mouth ulcers, hair loss, anxiety, fevers, night sweats and stomach pain.

Common (affects less than 1 person in 10)

- Changes in behaviour or depression, nightmares, Pain in your chest and feeling weak or dizzy. These could be signs of heart problems or low blood pressure.
- Blurred vision
- Shortness of breath or difficulty in breathing, cough, tiredness, fainting. These could be signs of inflammation in your lungs.

Other side effects include:

- Seeing or hearing things that are not there (hallucinations), confusion
- Difficulty in sleeping (insomnia)
- Dry eyes
- Slow heart rate. Swelling of feet or ankles. These could be signs that your heart is not working properly
- Episodes of muscle cramps or muscle pain especially when you walk or exercise

- Fingers and toes changing colour when cold and tingling or painful on warming up. This could be Raynaud's phenomenon.

Tell your doctor or pharmacist if any of the following side effects gets serious or lasts longer than a few days.

Very common (affects more than 1 person in 10)

- Lethargy

Common (affects less than 1 person in 10)

- Diarrhoea, feeling sick (nausea), headache

Other side effects include:

- Lack of interest in sexual activities (loss of libido)
- Being sick (vomiting)
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia)

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

- Hair loss (Alopecia)

Blood tests

Acebutolol can increase the levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly.

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 Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. How to store Acebutolol

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

Store below 30 °C.

Do not use this medicine after the expiry date which is stated on the label, carton and blister 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

- The active substance is acebutolol hydrochloride.
Each film-coated tablet contains 400 mg of acebutolol (as acebutolol hydrochloride)
- The other ingredients are
Tablet core: Lactose monohydrate, Maize starch, Povidone (K-30), Talc, Silica colloidal Anhydrous, Magnesium Stearate
Tablet coat: Hypromellose 6cp, Macrogol 6000, Titanium dioxide (E171)

What Acebutolol looks like and contents of the pack

Film-coated tablet.

White to off-white, oblong shaped biconvex film coated tablets having the length approximately 17.15 mm, diameter of body approximately 8.42 mm debossed with 'AC' and '4' separated with breakline on one side and plain on the other side.

The tablet can be divided into equal doses

Acebutolol film-coated tablets are available in blister packs.

Pack sizes:

Blister packs: 28, 30, 90 and 100 tablets.

Not all pack sizes may be marketed.

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This leaflet was last revised in 12/2023