

PACKAGE LEAFLET: INFORMATION FOR THE USER

Atenogen® 100mg Film-coated Tablets

Atenolol

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Atenogen Film-coated Tablets are and what they are used for

Atenogen Film Coated Tablets belong to a group of medicines called beta-blockers, and may be used to treat hypertension (high blood pressure) or to treat angina (a type of chest pain).

They may also be used to treat irregular heartbeats and to protect the heart following a heart attack.

2. Before you are take Atenogen Film-coated Tablets

Do not take Atenogen Film-coated Tablets

- if you are allergic (hypersensitive) to atenolol or any of the other ingredients of Atenogen Film-coated Tablets

(listed in section 6)

- if you have low blood pressure
- if you have been told that you have a heart block
- if you suffer from a tight, painful feeling in the chest at the time of rest (Prinzmetal's angina) or other heart problems
- if you have been told that you have very slow or irregular heart beat
- if you have difficulty in breathing, tiredness or ankle swelling due to heart disease
- if you suffer from a chest problem such as asthma or you have a family history of asthma
- if you suffer from blood circulation problems (which may cause your fingers and toes to tingle or turn pale or blue) or cramping pain causing limping
- if you have been told that you have higher than normal levels of acid in your blood (metabolic acidosis)
- if you suffer from an untreated tumour of the glands situated on top of the kidney which results in high blood pressure (phaeochromocytoma).

Speak to your doctor if this applies to you before you take Atenogen Film-coated Tablets

Take special care with Atenogen Film-coated Tablets

Tell your doctor before you take this medicine if you:

- have a history of allergic reactions
- have heart problems such as heart failure, untreated heart failure, poor heart function or heart block
- suffer with diabetes mellitus (low blood sugar levels may be hidden by this medicine)
- have impaired kidney or liver function
- are elderly
- have high levels of thyroid hormone in the body (thyrotoxicosis)
- have myasthenia gravis (weakness of the muscles)
- have skin problems (psoriasis).

If you are going to have an operation or an anaesthetic, please tell your doctor or dentist that you are taking Atenogen Film-coated Tablets as your heart beat might slow down too much and there may be an increased risk of developing low blood pressure.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Especially:

- anaesthetics
- disopyramide, quinidine, procainamide and amiodarone (to treat irregular heartbeat)
- medicines to treat diabetes including insulin
- non-steroidal anti-inflammatory drugs (NSAIDs) e.g. indometacin, ibuprofen for treating pain and fever
- digitalis glycosides such as digoxin (to treat heart condition)
- nifedipine, diltiazem, verapamil, prazosin, alfuzosin, clonidine, guanethidine, reserpine and terazosin (to treat high blood pressure)
- diuretics
- noradrenaline (to increase blood pressure).

Taking Atenogen Film-coated Tablets with food and drink

You are advised to avoid alcohol whilst taking this medicine.

Pregnancy and breast feeding

Tell your doctor *before* you are given this medicine if you are or think you may be pregnant or are planning to become pregnant or are breast feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Atenolol is unlikely to interfere with your ability to drive or to operate machines. However, if you notice any dizziness or tiredness whilst taking your medicine, do not drive or operate machines and ask your doctor for advice.

Important information about some of the ingredients of Atenogen Film-coated Tablets

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

3. How to take Atenogen Film-coated Tablets

Always take Atenogen Film-coated Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Atenogen Film coated Tablets should be swallowed whole with a little water.

The usual dose is shown below but your doctor may decide to reduce the dosage, for example, if you are elderly or if you have kidney problems.

Adults

High blood pressure: The total daily dose is 50 to 100mg to be taken as a single dose. It is usual to start treatment with one 50mg tablet daily; your doctor will decide if the dose needs to be increased to 100mg daily.

Angina: The usual dose is 100mg daily, taken as a single dose or as one 50mg tablet twice daily.

Irregular heartbeats: The usual maintenance dose is 50 to 100mg daily.

Protecting the heart following a heart attack: The usual dose is 100mg daily for long-term prevention.

Elderly

If you are elderly, your doctor may decide to reduce the dosage.

Children

Not recommended.

If you take more Atenogen Film-coated Tablets than you should

If you or if someone else take too much of this medicine or if you think that a child has swallowed some of the tablets, contact your nearest doctor or hospital immediately. Bring a sample of the tablets along with you.

If you forget to take Atenogen Film-coated Tablets

If you forget to take a dose, take it as soon as you remember and then take your next dose at the usual time. However, you must not take two days tablets on the same day.

If you stop taking Atenogen Film-coated Tablets

Do not stop taking the tablets unless your doctor tells you to. If you suffer from angina or a shortage of blood to the heart muscle and you need to stop this medicine for some reason, you should do so gradually over a few days. Ask your doctor for advice.

4. Possible side effects

Like all medicines Atenogen Film-coated Tablets can cause side-effects, although not everybody gets them.

The following side effects may happen with this medicine:

Allergic reactions:

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

Common (affects less than 1 in 10 people)

- You may notice that your pulse rate becomes slower while you are taking the tablets. 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 an abnormal heart beat, dizziness, tiredness or fainting)
- Numbness and spasm in your fingers which is followed by warmth and pain (Raynaud's disease)
- Mood changes
- 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
- Nightmares
- Feeling confused
- Changes in personality (psychoses) or hallucinations
- Headache
- Reduced numbers of platelets in your blood (this may make you bruise more easily)
- Purplish marks on your skin
- Jaundice (causing yellowing of your skin or the whites of your eyes)
- Besides these, the following conditions may get worse:
 - Psoriasis (a skin condition)
 - Being short of breath or having swollen ankles (if you have heart failure)
 - Asthma or breathing problems
 - Poor circulation.

Very rare (affects less than 1 in 10,000 people)

- Changes to some of the cells or other parts of your blood. Your doctor may take blood samples every so often to check whether Atenogen has had any effect on your blood.

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).

- Do not be concerned by this list of side effects. You may not get any of them.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

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

E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Atenogen Film-coated Tablets

Keep out of the reach and sight of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after 'EXP'.

The expiry date refers to the last day of the month

Do not store above 25°C.

Keep the tablets in the original package in order to protect from light.

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. Further information

What Atenogen Film-coated Tablets contains

The active substance is Atenolol.

Atenogen® 100mg Film-coated Tablets contain 100mg of Atenolol.

The other ingredients are lactose monohydrate, microcrystalline cellulose, sodium laurilsulfate, sodium starch glycolate type A, maize starch, magnesium stearate and gelatin.

The film coating solution for the 100 mg tablets contain ethylcellulose, propylene glycol and hypromellose and colourants titanium dioxide, sunset yellow (E110) and erythrosine.

What Atenogen Film-coated Tablets looks like and contents of pack

Atenogen® 100mg Film-coated Tablets-White coloured, slightly biconvex, film-coated debossed tablets, marked with AT/100 on one side and company logo on the reverse of tablet.

Atenogen® 100mg Film coated Tablets are available in blister packs of 28 tablets.

Marketing authorisation holder

Mercury Pharmaceuticals (Ireland) Ltd

Manufacturer

Mercury Pharmaceuticals Ltd

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