

## **Package leaflet: Information for the patient**

### **Tenormin 25 mg, 50 mg and 100 mg Film-coated Tablets atenolol**

**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.

#### **In this leaflet:**

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

### **1. What Tenormin is and what it is used for**

Tenormin contains a medicine called atenolol. This belongs to a group of medicines called beta-blockers. Tenormin is used to:

- Treat high blood pressure (hypertension).
- Help prevent chest pain (angina).
- Treat uneven heart beats (arrhythmias).
- Protect the heart in the early treatment after a heart attack (myocardial infarction).
- 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 Tenormin**

#### **Do not take Tenormin:**

- If you are allergic to atenolol or any of the other ingredients of this medicine (listed in section 6).
- If 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 or very uneven heart beats, very low blood pressure or very poor circulation.

- If 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 have been told that you have higher than normal levels of acid in your blood (metabolic acidosis).

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

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Tenormin:

- **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.**
- If you have a type of chest pain (angina) called Prinzmetal's angina.
- You have poor blood circulation or controlled heart failure.
- If you have first-degree heart block.
- If you have diabetes. Your medicine may change how you respond to having low blood sugar. You may feel your heart beating faster.
- If you have thyrotoxicosis (a condition caused by an overactive thyroid gland). Your medicine may hide the symptoms of thyrotoxicosis.
- If you have kidney problems. You may need to have some check-ups during your treatment.
- If you have psoriasis (a skin condition).

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

### **Other medicines and Tenormin**

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 and herbal medicines. This is because Tenormin can affect the way some other medicines work and some medicines can have an effect on Tenormin.

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

- Water tablets (diuretics), guanethidine, reserpine or other medicines for high blood pressure.
- Clonidine (for high blood pressure or migraine). If you are taking clonidine and Tenormin 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 heart beat).
- Digoxin (for heart problems).
- Adrenaline, also known as epinephrine (a medicine that stimulates the heart).
- Lidocaine, procainamide and noradrenaline, also known as norepinephrine (for heart problems).
- Ibuprofen or indometacin (for pain and inflammation).
- Insulin or medicines that you take by mouth for diabetes.
- Medicines to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy).

## Operations

If you go into hospital to have an operation, tell the anaesthetist or medical staff that you are taking Tenormin. This is because you can get low blood pressure (hypotension) if you are given certain anaesthetics while you are taking Tenormin.

## Pregnancy, breast-feeding and fertility

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. If you become pregnant whilst taking Tenormin, go back and talk to your doctor as soon as possible.

## 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.

## Tenormin 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 Tenormin

Always take this medicine exactly as your doctor or pharmacist has told you. 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.
- Swallow your Tenormin tablet whole with a drink of water.
- Try to take your tablet at the same time each day.

## Adults

Your doctor will decide how much Tenormin you should take each day, depending on your condition. The dose is normally taken once a day.

- **High blood pressure (hypertension):** the recommended dose is 50 mg to 100 mg a day.
- **Chest pain (angina):** the recommended dose is 50 mg to 100 mg a day or 50 mg twice a day.
- **Uneven heart beats (arrhythmias):** the recommended dose is 50 mg to 100 mg a day.
- **The early treatment of a heart attack (myocardial infarction):** the recommended dose is 50 mg twice a day. Your doctor may then change this to 100 mg once a day.
- **To help prevent another heart attack:** the recommended dose is 100 mg a day.

## **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 kidney problems**

If you have severe problems with your kidneys, your doctor may ask you to take Tenormin less often.

## **Use in children**

This medicine must not be given to children.

## **If you take more Tenormin than you should**

If you take more Tenormin than prescribed by your doctor, talk to a doctor or go to a hospital straight away. Take the medicine pack with you so that the tablets can be identified.

## **If you forget to take Tenormin**

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 Tenormin**

Do not stop taking Tenormin even if you are feeling well, without talking to your doctor. Then only do so gradually. Your doctor will tell you how to do this.

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.

### **Allergic reactions:**

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

### **Other possible side effects:**

#### **Common (may affect up to 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 (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 heart beat, dizziness, tiredness or fainting).
- Numbness and spasm in your fingers which is followed by warmth and pain (Raynaud's disease).
- Mood changes.
- Nightmares.
- Feeling confused.
- Changes in personality (psychoses) or hallucinations.
- Headache.
- 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.
- 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).

**Very rare (may affect up to 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 Tenormin 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).

**Conditions that may get worse**

If you have any of the following conditions, they may get worse when you start to take your medicine. This happens rarely affecting less than 1 in 1,000 people.

- Psoriasis (a skin condition).
- Being short of breath or having swollen ankles (if you have heart failure).
- Asthma or breathing problems.
- Poor circulation.

Do not be concerned by this list of side effects. You may not get any of them. If any of the side effects get 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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

### **Ireland**

HPRA Pharmacovigilance

Website: [www.hpra.ie](http://www.hpra.ie)

### **Malta**

ADR Reporting

Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)

## **5. How to store Tenormin**

- Keep this medicine out of the sight and reach of children.
- Do not store above 25°C. Store your tablets in the original package. Keep the blister strip in the carton. This will protect your medicine from light and moisture.
- Do not use this medicine after the expiry date which is stated on the blister strip and carton. 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 Tenormin contains**

The active substance is atenolol. Three different strengths are available.

Each Tenormin 25 mg Film-coated Tablet contains 25 mg of atenolol.

Each Tenormin 50 mg Film-coated Tablet contains 50 mg of atenolol.

Each Tenormin 100 mg Film-coated Tablet contains 100 mg of atenolol.

The other ingredients contained in all strengths of the tablets are: gelatin, heavy magnesium carbonate, maize starch, magnesium stearate, hypromellose, sodium laurilsulfate, titanium dioxide (E171) and glycerol. See section 2 'Tenormin contains sodium' for more information.

### **What Tenormin looks like and contents of the pack**

Tenormin 25 mg Film-coated Tablets are round and white with 25 embossed on one side and plain on the other side. They come in a pack (blister strip) containing 28 tablets.

Tenormin 50 mg Film-coated Tablets are round and white with 50 embossed on one side and bisected on the other side. They come in a pack (blister strip) containing 28 tablets.

Tenormin 100 mg Film-coated Tablets are round and white with 100 embossed on one side and bisected on the other side. They come in a pack (blister strip) containing 28 tablets.

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

The Marketing Authorisations for Tenormin 25 mg, 50 mg and 100 mg Film-coated Tablets marketed in Ireland and Malta are held by AstraZeneca AB, SE-151 85 Södertälje, Sweden.

Tenormin 25 mg, 50 mg and 100 mg Film-coated Tablets are manufactured by AstraZeneca AB, Gärtunavägen, SE-151 85 Södertälje, Sweden.

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