

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

### **Tenormin® Injection 0.5 mg/ml**

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.

#### **What is in this leaflet**

1. What Tenormin is and what it is used for
2. What you need to know before you have Tenormin
3. How to have 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 uneven heart beats (arrhythmias).
- Protect the heart in the early treatment after a heart attack (myocardial infarction).

It works by making your heart beat more slowly and with less force.

### **2. What you need to know before you have Tenormin**

#### **Do not have Tenormin:**

- If you are allergic to atenolol or any of the other ingredients in your medicine (see Section 6: Further information).
- 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 are being treated for phaeochromocytoma, your doctor will give you another medicine, called an alpha-blocker, to take as well as your Tenormin.

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

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

### **Warnings and precautions**

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

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before having 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:

- 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).
- 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 having Tenormin. This is because you can get low blood pressure (hypotension) if you are given certain anaesthetics while you are having 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.

## **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 having this medicine, do not drive or use any tools or machines.

## **3. How to have Tenormin**

This medicine will be given to you by a doctor or nurse. It will be given to you as an injection.

The dose depends on your illness, and how bad it is, your age and weight and how well your kidneys are working.

### **Use in children**

This medicine must not be given to children.

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

If you think you have been given too much of this medicine, talk to your doctor or nurse straight away.

### **If you forget to have Tenormin**

If you think you have not had a dose at the right time, talk to your doctor or nurse straight away.

### **If you stop having Tenormin**

Your doctor or nurse will let you know when to stop having this medicine.

## **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 having the injection. 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 may 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).
- 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).
- Depression.

**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.

## 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 Yellow Card Scheme. Website: [www.mhra.gov.uk/yellowcard](http://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 Tenormin

- The doctor and hospital pharmacist are responsible for storing, using and disposing of Tenormin correctly.
- Keep this medicine out of sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the ampoule label and carton. The expiry date refers to the last day of that month.
- Do not store above 25°C. Store your medicine in the original package. Keep the ampoules in the carton.

## 6. Contents of the pack and other information

### What Tenormin contains

The active substance is atenolol. Tenormin contains 5 mg (milligrams) of atenolol in 10 ml (millilitres) of injection.

The other ingredients are citric acid, sodium chloride, sodium hydroxide and water for injection.

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

Tenormin Injection 0.5 mg/ml is a clear, colourless solution in a clear glass ampoule. It comes in a pack containing 10 ampoules. Each ampoule contains 10 ml of solution.

### Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Tenormin Injection 0.5 mg/ml is held by Atnahs Pharma UK Limited, Sovereign House, Miles Gray Road, Basildon, Essex, SS14 3FR, United Kingdom. Tenormin Injection 0.5 mg/ml is manufactured by Cenexi, 52 Rue Marcel et Jacques Gaucher 94120 Fontenay-sous-Bois, France.

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only)

Please be ready to give the following information:

<b>Product name</b>	<b>Tenormin Injection 0.5 mg/ml</b>
<b>Reference number</b>	<b>PL 43252/0041</b>

This is a service provided by the Royal National Institute of Blind People.

**This leaflet was revised in July 2021.**

## MEDICAL INFORMATION LEAFLET

TENORMIN® INJECTION 0.5 mg/ml

atenolol

### 1. Name of the medicinal product

‘Tenormin’ Injection 0.5 mg/ml

### 2. Qualitative and quantitative composition

Atenolol 0.5 mg/ml (5 mg in 10 ml).

For the full list of excipients, see section 6.1.

### 3. Pharmaceutical form

Solution for injection or infusion.

Type I clear glass ampoules containing a clear, colourless, sterile solution.

### 4. Clinical particulars

#### 4.1 Therapeutic indications

Management of arrhythmias and for the early intervention treatment of acute myocardial infarction.

#### 4.2 Posology and method of administration

##### Posology

The dose must always be adjusted to individual requirements of the patients, with the lowest possible starting dosage. The following are guidelines:

##### **Adults**

##### **Cardiac arrhythmias**

A suitable initial dose of Tenormin is 2.5 mg (5 ml) injected intravenously over a 2.5 minute period (i.e. 1 mg/minute). This may be repeated at 5 minute intervals until a response is observed up to a maximum dosage of 10 mg. If Tenormin is given by infusion, 0.15 mg/kg bodyweight may be administered over a 20 minute period. If required, the injection or infusion may be repeated every 12 hours.

Having controlled the arrhythmias with intravenous Tenormin, a suitable oral maintenance dosage is 50 to 100 mg daily (see prescribing information for Tenormin and Tenormin LS tablets).

##### **Myocardial infarction**

For patients suitable for treatment with intravenous beta-blockade and presenting within 12 hours of the onset of chest pain, Tenormin 5–10 mg should be given by slow intravenous injection (1 mg/minute) followed by Tenormin 50 mg orally about 15 minutes later, provided no untoward effects have occurred from the intravenous dose. This should be followed by a further 50 mg orally 12 hours after the intravenous dose, and then 12 hours later by 100 mg

orally, once daily. If bradycardia and/or hypotension requiring treatment, or any other untoward effects occur, Tenormin should be discontinued.

### **Elderly**

Dosage requirements may be reduced, especially in patients with impaired renal function.

### **Paediatric population**

There is no paediatric experience with Tenormin and for this reason it is not recommended for use in children.

### **Renal impairment**

Since Tenormin is excreted via the kidneys, dosage should be adjusted in cases of severe impairment of renal function.

No significant accumulation of Tenormin occurs in patients who have a creatinine clearance greater than 35 ml/min/1.73 m<sup>2</sup> (normal range is 100–150 ml/min/1.73 m<sup>2</sup>).

For patients with a creatinine clearance of 15–35 ml/min/1.73 m<sup>2</sup> (equivalent to serum creatinine of 300–600 micromol/litre), the oral dose should be 50 mg daily and intravenous dose should be 10 mg once every two days.

For patients with a creatinine clearance of less than 15 ml/min/1.73 m<sup>2</sup> (equivalent to serum creatinine of greater than 600 micromol/litre), the oral dose should be 25 mg daily or 50 mg on alternate days and the intravenous dose should be 10 mg once every four days.

Patients on haemodialysis should be given 50 mg orally after each dialysis; this should be done under hospital supervision as marked falls in blood pressure can occur.

### **Method of administration**

Administered by the intravenous route.

### **4.3 Contraindications**

Tenormin, as with other beta-blockers, should not be used in patients with any of the following:

- hypersensitivity to the active substance, or to any of the excipients listed in section 6.1
- cardiogenic shock
- uncontrolled heart failure
- sick sinus syndrome
- second- or third-degree heart block
- untreated phaeochromocytoma
- metabolic acidosis
- bradycardia (<45 bpm)
- hypotension
- severe peripheral arterial circulatory disturbances.

### **4.4 Special warnings and precautions for use**

Tenormin as with other beta-blockers:

- Should not be withdrawn abruptly. The dosage should be withdrawn gradually over a period of 7–14 days, to facilitate a reduction in beta-blocker dosage. Patients should be followed during withdrawal, especially those with ischaemic heart disease.
- When a patient is scheduled for surgery, and a decision is made to discontinue beta-blocker therapy, this should be done at least 24 hours prior to the procedure. The risk-benefit assessment of stopping beta-blockade should be made for each patient. If treatment is continued, an anaesthetic with little negative inotropic activity should be selected to minimise the risk of myocardial depression. The patient may be protected against vagal reactions by intravenous administration of atropine.
- Although contraindicated in uncontrolled heart failure (see section 4.3), may be used in patients whose signs of heart failure have been controlled. Caution must be exercised in patients whose cardiac reserve is poor.
- May increase the number and duration of angina attacks in patients with Prinzmetal's angina due to unopposed alpha-receptor mediated coronary artery vasoconstriction. Tenormin is a beta<sub>1</sub>-selective beta-blocker; consequently, its use may be considered although utmost caution must be exercised.
- Although contraindicated in severe peripheral arterial circulatory disturbances (see section 4.3), may also aggravate less severe peripheral arterial circulatory disturbances.
- Due to its negative effect on conduction time, caution must be exercised if it is given to patients with first-degree heart block.
- May mask the symptoms of hypoglycaemia, in particular, tachycardia.
- May mask the signs of thyrotoxicosis.
- Will reduce heart rate as a result of its pharmacological action. In the rare instances when a treated patient develops symptoms which may be attributable to a slow heart rate and the pulse rate drops to less than 50–55bpm at rest, the dose should be reduced.
- May cause a more severe reaction to a variety of allergens when given to patients with a history of anaphylactic reaction to such allergens. Such patients may be unresponsive to the usual doses of adrenaline (epinephrine) used to treat the allergic reactions.
- May cause a hypersensitivity reaction including angioedema and urticaria.
- Should be used with caution in the elderly, starting with a lesser dose (see section 4.2).

Since Tenormin is excreted via the kidneys, dosage should be reduced in patients with a creatinine clearance of below 35ml/min/1.73 m<sup>2</sup>.

Although cardioselective (beta<sub>1</sub>) beta-blockers may have less effect on lung function than non-selective beta-blockers, as with all beta-blockers, these should be avoided in patients with reversible obstructive airways disease, unless there are compelling clinical reasons for their use. Where such reasons exist, Tenormin may be used with caution. Occasionally, some increase in airways resistance may occur in asthmatic patients however, and this may usually be reversed by commonly used dosage of bronchodilators such as salbutamol or isoprenaline. The label and patient information leaflet for this product state the following warning: "If you have ever had asthma or wheezing, you should not take this medicine unless you have discussed these symptoms with the prescribing doctor".

As with other beta-blockers, in patients with a phaeochromocytoma, an alpha-blocker should be given concomitantly.

#### **4.5 Interaction with other medicinal products and other forms of interaction**

Combined use of beta-blockers and calcium channel blockers with negative inotropic effects, e.g. verapamil and diltiazem, can lead to an exaggeration of these effects particularly in patients with impaired ventricular function and/or sinoatrial or atrioventricular conduction abnormalities. This may result in severe hypotension, bradycardia and cardiac failure. Neither the beta-blocker nor the calcium channel blocker should be administered intravenously within 48 hours of discontinuing the other.

Concomitant therapy with dihydropyridines, e.g. nifedipine, may increase the risk of hypotension, and cardiac failure may occur in patients with latent cardiac insufficiency.

Digitalis glycosides, in association with beta-blockers, may increase atrioventricular conduction time.

Beta-blockers may exacerbate the rebound hypertension which can follow the withdrawal of clonidine. If the two drugs are co-administered, the beta-blocker should be withdrawn several days before discontinuing clonidine. If replacing clonidine by beta-blocker therapy, the introduction of beta-blockers should be delayed for several days after clonidine administration has stopped. (See also prescribing information for clonidine.)

Class I anti-arrhythmic drugs (e.g. disopyramide) and amiodarone may have a potentiating effect on atrial-conduction time and induce negative inotropic effect.

Concomitant use of sympathomimetic agents, e.g. adrenaline (epinephrine), may counteract the effect of beta-blockers.

Concomitant use with insulin and oral antidiabetic drugs may lead to the intensification of the blood sugar lowering effects of these drugs. Symptoms of hypoglycaemia, particularly tachycardia, may be masked (see section 4.4).

Concomitant use of prostaglandin synthetase-inhibiting drugs e.g. ibuprofen and indometacin may decrease the hypotensive effects of beta-blockers.

Caution must be exercised when using anaesthetic agents with Tenormin. The anaesthetist should be informed and the choice of anaesthetic should be an agent with as little negative inotropic activity as possible. Use of beta-blockers with anaesthetic drugs may result in attenuation of the reflex tachycardia and increase the risk of hypotension. Anaesthetic agents causing myocardial depression are best avoided.

#### **4.6 Fertility, pregnancy and lactation**

Caution should be exercised when Tenormin is administered during pregnancy or to a woman who is breast-feeding.

##### **Pregnancy**

Tenormin crosses the placental barrier and appears in the cord blood. No studies have been performed on the use of Tenormin in the first trimester and the possibility of foetal injury cannot be excluded. Tenormin has been used under close supervision for the treatment of hypertension in the third trimester. Administration of Tenormin to pregnant women in the management of mild to moderate hypertension has been associated with intra-uterine growth retardation.

The use of Tenormin in women who are, or may become, pregnant requires that the anticipated benefit be weighed against the possible risks, particularly in the first and second

trimesters, since beta-blockers, in general, have been associated with a decrease in placental perfusion which may result in intra-uterine deaths, immature and premature deliveries.

### **Breast-feeding**

There is significant accumulation of Tenormin in breast milk.

Neonates born to mothers who are receiving Tenormin at parturition or breast-feeding may be at risk of hypoglycaemia and bradycardia.

### **4.7 Effects on ability to drive and use machines**

Tenormin has no or negligible influence on the ability to drive and use machines. However, it should be taken into account that occasionally dizziness or fatigue may occur.

### **4.8 Undesirable effects**

Tenormin is well tolerated. In clinical studies, the undesired events reported are usually attributable to the pharmacological actions of atenolol.

The following undesired events, listed by body system, have been reported with the following frequencies: very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $< 1/10$ ), uncommon

( $\geq 1/1,000$  to  $< 1/100$ ), rare ( $\geq 1/10,000$  to  $< 1/1,000$ ), very rare ( $< 1/10,000$ ) including isolated reports, not known (cannot be estimated from the available data).

<b>System Organ Class</b>	<b>Frequency</b>	<b>Undesirable Effect</b>
Blood and lymphatic system disorders	Rare	Purpura, thrombocytopenia
Psychiatric disorders	Uncommon	Sleep disturbances of the type noted with other beta-blockers
	Rare	Mood changes, nightmares, confusion, psychoses and hallucinations
	Not known	Depression
Nervous system disorders	Rare	Dizziness, headache, paraesthesia
Eye disorders	Rare	Dry eyes, visual disturbances
Cardiac disorders	Common	Bradycardia
	Rare	Heart failure deterioration, precipitation of heart block
Vascular disorders	Common	Cold extremities
	Rare	Postural hypotension which may be associated with syncope, intermittent claudication may be increased if already present, in susceptible

		patients Raynaud's phenomenon
Respiratory, thoracic and mediastinal disorders	Rare	Bronchospasm may occur in patients with bronchial asthma or a history of asthmatic complaints
Gastrointestinal disorders	Common	Gastrointestinal disturbances
	Rare	Dry mouth
Hepato-biliary disorders	Uncommon	Elevations of transaminase levels
	Rare	Hepatic toxicity including intrahepatic cholestasis
Skin and subcutaneous tissue disorders	Rare	Alopecia, psoriasiform skin reactions, exacerbation of psoriasis, skin rashes
	Not known	Hypersensitivity reactions, including angioedema and urticaria
Musculoskeletal and connective tissue disorders	Not known	Lupus-like syndrome
Reproductive system and breast disorders	Rare	Impotence
General disorders and administration site conditions	Common	Fatigue
Investigations	Very rare	An increase in ANA (Antinuclear Antibodies) has been observed, however the clinical relevance of this is not clear

Discontinuance of the drug should be considered if, according to clinical judgement, the well-being of the patient is adversely affected by any of the above reactions.

#### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme. Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

#### **4.9 Overdose**

The symptoms of overdosage may include bradycardia, hypotension, acute cardiac insufficiency and bronchospasm.

General treatment should include: close supervision, treatment in an intensive care ward; the use of gastric lavage; activated charcoal and a laxative to prevent absorption of any drug still present in the gastrointestinal tract; the use of plasma or plasma substitutes to treat hypotension and shock. The use of haemodialysis or haemoperfusion may be considered.

Excessive bradycardia can be countered with atropine 1–2 mg intravenously and/or a cardiac pacemaker. If necessary, this may be followed by a bolus dose of glucagon 10 mg intravenously. If required, this may be repeated or followed by an intravenous infusion of glucagon 1–10 mg/hour depending on response. If no response to glucagon occurs or if glucagon is unavailable, a beta-adrenoceptor stimulant such as dobutamine 2.5 to 10 micrograms/kg/minute by intravenous infusion may be given. Dobutamine, because of its positive inotropic effect could also be used to treat hypotension and acute cardiac insufficiency. It is likely that these doses would be inadequate to reverse the cardiac effects of beta-blocker blockade if a large overdose has been taken. The dose of dobutamine should therefore be increased if necessary to achieve the required response according to the clinical condition of the patient.

Bronchospasm can usually be reversed by bronchodilators.

## **5 Pharmacological properties**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Beta-blocking agents, plain, selective, ATC code: CO7A B03.

#### **Mechanism of action**

Atenolol is a beta-blocker which is beta<sub>1</sub>-selective, (i.e. acts preferentially on beta<sub>1</sub>-adrenergic receptors in the heart). Selectivity decreases with increasing dose.

Atenolol is without intrinsic sympathomimetic and membrane-stabilising activities and as with other beta-blockers, has negative inotropic effects (and is therefore contraindicated in uncontrolled heart failure).

As with other beta-blockers, the mode of action of atenolol in the treatment of hypertension is unclear.

It is probably the action of atenolol in reducing cardiac rate and contractility which makes it effective in eliminating or reducing the symptoms of patients with angina.

#### **Clinical efficacy and safety**

It is unlikely that any additional ancillary properties possessed by S(-) atenolol, in comparison with the racemic mixture, will give rise to different therapeutic effects.

Tenormin is effective and well-tolerated in most ethnic populations although the response may be less in black patients.

The narrow dose range and early patient response to Tenormin ensure that the effect of the drug in individual patients is quickly demonstrated. Tenormin is compatible with diuretics, other hypotensive agents and antianginals (see section 4.5). Since it acts preferentially on beta-adrenergic receptors in the heart, Tenormin may, with care be used successfully in the treatment of patients with respiratory disease who cannot tolerate non-selective beta-adrenoceptor blocking drugs.

Early intervention with Tenormin in acute myocardial infarction reduces infarct size and decreases morbidity and mortality. Fewer patients with a threatened infarction progress to frank

infarction; the incidence of ventricular arrhythmias is decreased and marked pain relief may result in reduced need of opiate analgesics. Early mortality is decreased. Tenormin is an additional treatment to standard coronary care.

## **5.2 Pharmacokinetic properties**

### **Absorption**

Following intravenous administration, the blood levels of atenolol decay tri-exponentially with an elimination half-life of about 6 hours. Throughout the intravenous dose range of 5 to 10 mg the blood level profile obeys linear pharmacokinetics and beta-adrenoceptor blockade is still measurable 24 hours after a 10 mg intravenous dose.

Absorption of atenolol following oral dosing is consistent but incomplete (approximately 40–50%) with peak plasma concentrations occurring 2–4 hours after dosing. The atenolol blood levels are consistent and subject to little variability. There is no significant hepatic metabolism of atenolol and more than 90% of that absorbed reaches the systemic circulation unaltered.

### **Distribution**

Atenolol penetrates tissues poorly due to its low lipid solubility and its concentration in brain tissue is low. Plasma protein binding is low (approximately 3%).

### **Elimination**

The plasma half-life is about 6 hours but this may rise in severe renal impairment since the kidney is the major route of elimination.

## **5.3 Preclinical safety data**

Atenolol is a drug on which extensive clinical experience has been obtained. Relevant information for the prescriber is provided elsewhere in the Prescribing Information.

## **6 Pharmaceutical particulars**

### **6.1 List of excipients**

Citric acid

Sodium chloride

Sodium hydroxide

Water for Injection

### **6.2 Incompatibilities**

None known.

### **6.3 Shelf-life**

36 months.

#### **6.4 Special precautions for storage**

Do not store above 25°C. Keep the container in the outer carton.

#### **6.5 Nature and contents of container**

Glass ampoules.

10 ml ampoules are packed in boxes of 10.

#### **6.6 Special precautions for disposal and other handling**

Use as instructed by the prescriber.

Tenormin Injection is compatible with sodium chloride intravenous infusion (0.9 %w/v) and Glucose Intravenous Infusion BP (5 % w/v).

### **7 Marketing Authorisation holder**

Atnahs Pharma UK Limited.  
Sovereign House  
Miles Gray Road  
Basildon, Essex  
SS14 3FR  
United Kingdom.

**This leaflet was last revised in July 2021.**