# Summary of Product Characteristics

## 1. Name of the medicinal product

Tenormin 50 mg Tablets

## 2. Qualitative and quantitative composition

Atenolol 50 mg.

For the full list of excipients, see section 6.1.

## 3. Pharmaceutical form

Film-coated tablet.

White, round, biconvex, film-coated tablets of diameter 8 mm, which are intagliated with 50 on one face and bisected on the reverse face.

## 4. Clinical particulars

### 4.1 Therapeutic indications

Tenormin is indicated in the treatment of:

- Management of hypertension.
- Management of angina pectoris.
- Management of cardiac arrhythmias.
- Management of myocardial infarction. Early intervention in the acute phase.

### 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**

**Hypertension**

One tablet daily. Most patients respond to 100 mg daily given orally as a single dose. Some patients, however, will respond to 50 mg given as a single daily dose.

The effect will be fully established after one to two weeks. A further reduction in blood pressure may be achieved by combining Tenormin with other antihypertensive agents. For example, co-administration of Tenormin with a diuretic, as in Tenoretic provides a highly effective and convenient antihypertensive therapy.

**Angina**

Most patients with angina pectoris will respond to 100 mg given orally once daily or 50 mg given twice daily. It is unlikely that additional benefit will be gained by increasing the dose.

**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). (See also prescribing information for Tenormin Injection.) 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 50–100 mg daily, given as a single dose.

**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, the 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 $m^2$ (normal range is 100–150 ml/min/1.73 $m^2$).

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

For patients with a creatinine clearance of less than 15 ml/min/1.73 $m^2$ (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**

For administration by the oral 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 $beta_1$-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. Beta-blockers could further increase the risk of severe hypoglycaemia when used concurrently with sulfonylureas. Diabetic patients should be advised to carefully monitor blood glucose levels. (see Section 4.5).

• 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 50–55 bpm 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 35 ml/min/1.73 $m^2$.

Although cardioselective ($beta_1$) 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.

**Sodium Content**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that it is to say essentially 'sodium-free'.

## 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. The concomitant use of beta-blockers with sulfonylureas could increase the risk of severe hypoglycaemia. 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 growth retardation, intra-uterine deaths, abortion, 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 (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100), rare (≥1/10,000 to <1/1,000), very rare (<1/10,000) including isolated reports, not known (cannot be estimated from the available data).

| **System Organ Class** | **Frequency** | **Undesirable Effect** |
|---|---|---|
| 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 |
| Hepatobiliary 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 National Regulatory Authority.

## 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 possible uses 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 $beta_1$-selective, (i.e. acts preferentially on $beta_1$-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.

Tenormin is effective for at least 24 hours after a single oral dose. The drug facilitates compliance by its acceptability to patients and simplicity of dosing. The narrow dose range and early patient response 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-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-blockers.

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**

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**

Gelatin

Glycerol

Heavy Magnesium Carbonate

Magnesium Stearate

Maize Starch

Hypromellose

Sodium lauryl sulfate

Titanium Dioxide (E171)

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf life**

24 months.

**6.4 Special precautions for storage**

Do not store above 30 °C.

Store in the original package. Keep the container in the outer carton.

**6.5 Nature and contents of container**

Aluminium PVC blister strips of 14 tablets: 28 Tablets

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

No special requirements for disposal.

**7. Marketing authorisation holder**

AstraZeneca UK Operations,
Silk Road Business Park, Macclesfield, Cheshire SK10 2NA,

United Kingdom.

**8. Marketing authorisation number(s)**

H2011/3551/R1

**9. Date of first authorisation/renewal of the authorisation**

Date of latest renewal: 24th November 2025

**10. Date of revision of the text**

03/03/2026