For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

BETACARD

1. Generic Name

Atenolol Tablets I.P. 25 mg

Atenolol Tablets I.P. 50 mg

2. Qualitative and quantitative Composition:

BETACARD-25

Each film coated tablet contains:

Atenolol I.P….....25mg

Colours: Lake of Sunset Yellow, Titanium Dioxide I.P.

The Excipients Used are Starch, Dibasic Calcium, Talc, Sodium Lauryl Sulphate, Sodium CMC, Lake of Sunset Yellow, Hydroxy Propyl Methyl Cellulose, Colloidal Silicon Dioxide, Titanium Dioxide, PEG-6000.

BETACARD-50

Each film coated tablet contains:

Atenolol I.P….....50 mg

Colours: Yellow Oxide of Iron & Titanium Dioxide I.P.

Excipients ……...q.s.

The Excipients Used are Corn Starch, Dibasic Calcium Pho, Magnesium Stearate, Talc, Sodium Lauryl Sulfate/Sulphate, Sodium Carboxy Methyl Cellulose, Ferric Oxide Yellow, Hydroxy Propyl Methyl Cellulose, Colloidal Silicon Dioxide, Titanium Dioxide, PEG-6000

3. Dosage form and strength

Dosage form: Film-coated Tablet

Strength: Atenolol 25 mg and 50 mg.

4. Clinical particulars

4.1. Therapeutic indication

Atenolol is indicated in the treatment of:

1. Management of hypertension

2. Management of angina pectoris

3. Management of cardiac arrhythmias

4. 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

Usual Dose: One tablet daily. Most patients respond to 100 mg daily given orally as a single dose. Some patients, however, will respond to 50 mg as a single daily dose. The effect will be fully established after administration for one to two weeks. A further reduction in blood pressure, if desired, may be achieved by combining atenolol with other antihypertensive agents. For example, co-administration of Atenolol tablet with a diuretic, which 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 twice daily. It is unlikely that additional benefit will be gained by increasing the dose.

Cardiac arrhythmias

A suitable initial dose of Atenolol 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 Atenolol 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 atenolol, a suitable oral maintenance dosage is 50 - 100 mg daily, given as a single dose.

Myocardial infarction

For patients suitable for treatment with intravenous β-blockage and presenting within 12 hours of the onset of chest pain, Atenolol 5-10 mg should be given by slow intravenous injection (1 mg/minute) followed by Atenolol 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 given once daily.

If bradycardia and/or hypotension requiring treatment, or any other side effects occur, atenolol therapy should be discontinued.

Elderly Patients

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

Paediatric population

Not recommended for use in children as there is no paediatric experience with atenolol.

Renal impairment

Since atenolol is excreted via the kidneys, dosage should be adjusted in cases of severe impairment of renal function. No significant accumulation of atenolol occurs in patients who have a creatinine clearance greater than 35 ml/min/1.73m^2 (normal range is 100-150 ml/min/1.73m^2).

For patients with a creatinine clearance of 15-35 ml/min/1.73m^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 < 15 ml/min/1.73m^2 (equivalent to serum creatinine of > 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 Oral use.

4.3. Contraindications

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

- Hypersensitivity to atenolol or to any of the excipients.
- Hypotension.
- Severe peripheral arterial circulatory disturbances.
- Untreated phaeochromocytoma.
- Metabolic acidosis.
- Uncontrolled heart failure.
- Cardiogenic shock.
- Heart block - 2nd or 3rd degree.
- Sinus bradycardia (heart rate less than 45 beats per minute).
- Sick sinus syndrome.

4.4. Special warnings and precautions for use

Respiratory Disorders: Although cardioselective (β1) 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, Atenolol 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.

Patient information leaflets and labels will carry the following warnings: If you have ever had asthma or wheezing, do not take this medicine without first checking with your doctor.

Heart failure: Although atenolol is contra-indicated in uncontrolled heart failure, it may be used in patients whose signs of heart failure have been controlled. Caution must be exercised in patients whose cardiac reserve is poor.

Prinzmetal's angina: May increase the number and duration of angina attacks in patients with Prinzmetal's angina due to unopposed α-receptor mediated coronary artery vasoconstriction. Atenolol is a β1-selective beta-blocker; consequently, its use may be considered although utmost caution must be exercised.

Bradycardia: Beta-blockers 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 decreases to less than 50-55 beats per minute when the patient is at rest, the dose should be reduced.

Elderly: These patients should be treated with caution, starting with a lower dose.

First Degree Heart Block: Due to its negative effect on conduction time, beta blockers should only be given with caution to such patients.

Ischaemic Heart disease: Treatment should not be discontinued abruptly. The dosage should be withdrawn gradually over a period of 1-2 weeks, to facilitate a reduction in beta-blocker dosage. Patients should be followed during withdrawal, especially those with ischaemic heart diseases.

Anaesthesia: If it is thought necessary to withdraw β-blocker therapy before surgery, this should be done gradually and completed at least 24 hours before anaesthesia. The risk-benefit assessment of stopping β-blockade should be made for each patient. If beta- blockers are not discontinued before anaesthesia, the anaesthetist should be made aware of the beta-blocker therapy, and 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.

Diabetics: Atenolol may mask the symptoms of hypoglycaemia, in particular, tachycardia.

Kidney Insufficiency: Since atenolol is excreted via the kidneys, dosage should be reduced in patients with a creatinine clearance of below 35 ml/min/1.73 m^2.

Peripheral Arterial Circulatory Disease: Although contra-indicated in severe peripheral circulatory disturbances, atenolol may also aggravate less severe peripheral circulatory disturbances.

Allergies: Beta-blockers may cause a hypersensitivity reaction including angioedema and urticaria. 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) that is used to treat allergic reactions.

Thyrotoxicosis: Atenolol as with other beta-blockers may mask the signs of thyrotoxicosis.

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

This medicine contains sunset yellow aluminium lake (E110) which may cause allergic reactions.

Sodium: This medicine contains less than 1mmol sodium (23 mg) per tablet, that is to say essentially "sodium free".

4.5. Drugs interactions

Anaesthetics: Caution must be used when using anaesthetic agents with atenolol. Use of atenolol with anaesthetics may result in attenuation of the risk of reflex tachycardia and increase the risk of hypotension. The anaesthetist should be informed and the choice of anaesthetic should be an agent with as little negative inotropic activity as possible. Anaesthetic agents causing myocardial depression are best avoided.

Antidiabetics: Concomitant use of atenolol 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.

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

Calcium-channel blocking agents: Combined use of beta-blockers and calcium channel blocking agents with negative inotropic effects such as diltiazem and verapamil, 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.

Clonidine: Caution should be exercised when transferring patients from clonidine to beta-adrenoceptor blocking drugs. Beta-blockers may exacerbate the rebound hypertension which can follow the withdrawal of clonidine. If beta-adrenoceptor blocking drugs and clonidine are given concurrently, 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.

Anti-arrhythmics: concurrent use of atenolol with class-I anti-arrhythmic agents such as disopyramide or amiodarone may have a potentiating effect on atrial-conduction time and induce negative inotropic effect.

Digitalis glycosides: In association with beta-blockers, may increase AV conduction time.

Sympathomimetics: Concomitant use of sympathomimetic agents eg. adrenaline (epinephrine), may counteract the effect of beta-blockers.

4.6. Use in special populations (such as pregnant women, lactating women, paediatric patients, geriatric patients etc.)

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

Pregnancy

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

The use of Atenolol 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 Atenolol in breast milk. Neonates born to mothers who are receiving Atenolol at parturition or breast-feeding may be at risk of hypoglycaemia and bradycardia.

4.7. Effects on ability to drive and use machines

Atenolol 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

Atenolol 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 during treatment with atenolol and other beta blockers with the following frequencies: very common (>1/10),

common (>1/100 to <1/10), uncommon (>1/1000 to <1/100), rare (>1/10,000 to <1/1000), very rare (<1/10,000) including isolated reports, not known (cannot be estimated from the available data).

Blood and lymphatic system disorders:

Rare: Thrombocytopenia, Purpura.

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 disorder:

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 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. Report suspected adverse reactions via any point of contact available at www.torrentpharma.com.

4.9. Overdose

Symptoms: 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 and plasma substitutes to treat hypotension and shock. The possible uses of haemodialysis or haemoperfusion may be considered.

Excessive bradycardia and hypotension may be countered by 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-adrenoreceptor 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-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. Mechanism of Action

Atenolol is a β-adrenoceptor blocking drug which is β1- selective (ie. acts preferentially on beta1-adrenergic receptors in the heart). Selectivity decreases with increasing dose. It is without intrinsic sympathomimetic and membrane stabilising activities as with other β-blockers, has negative inotropic effects (and is therefore contraindicated in uncontrolled heart failure).

As with other β-adrenoceptor blocking drugs, it’s mode of action 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.

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.

5.2. Pharmacodynamic properties

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

Atenolol 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. Atenolol is compatible with diuretics, other hypotensive agents and antianginals. Since it acts preferentially on beta-receptors in the heart, Atenolol may, with care, be used successfully in the treatment of patients with respiratory disease, who cannot tolerate non-selective beta-blockers.

Early intervention with atenolol 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.

Atenolol is an additional treatment to standard coronary care.

5.3. 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.

6. Nonclinical properties

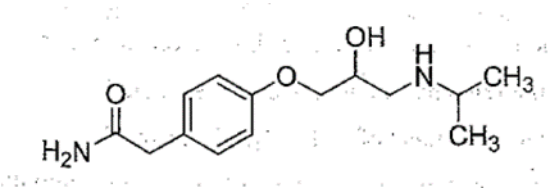
6.1. Animal Toxicology or Pharmacology

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

7. Description

Atenolol

A white or almost white powder. The molecular formula for Atenolol is $C_{14}H_{22}N_2O_3$ and the molecular weight is 266.3 g/mol. The chemical name is (RS)-4-(2-hydroxy-3-isopropylaminopropoxy) phenylacetamide. and its structural formula is:



BETACARD – 25

Atenolol tablets are orange coloured, round, biconvex film coated tablets with bisecting line on one side. The excipients used are Starch, Dibasic Calcium, Talc, Sodium Lauryl Sulphate, Sodium CMC, Lake of Sunset Yellow, Hydroxy Propyl Methyl Cellulose, Colloidal Silicon Dioxide, Titanium Dioxide, PEG-6000

BETACARD – 50

Atenolol tablets are light yellow to light brown coloured, round, biconvex, film coated tablets, with bisecting line on one side. The excipients used are Corn Starch, Dibasic Calcium Pho, Magnesium Stearate, Talc, , Sodium Lauryl Sulfate/Sulphate, Sodium Carboxy Methyl Cellulose, Ferric Oxide Yellow, Hydroxy Propyl Methyl Cellulose, Colloidal Silicon Dioxide, Titanium Dioxide, PEG-6000

8. Pharmaceutical particulars

8.1. Incompatibilities

Not applicable.

8.2. Shelf-life

Do not use later than the date of expiry.

8.3. Packaging information

BETACARD-25, BETACARD-50 is available in Blister strip of 14 Tablets.

8.4. Storage and handing instructions.

KEEP IN COOL DRY PLACE, PROTECTED FROM LIGHT.

9. Patient Counselling Information

Ask the patients to inform the treating physicians in case of any of the below:

- Have any allergies.
- Have kidney or liver problems.
- Are pregnant or plan to become pregnant.
- Are breastfeeding or plan to breastfeed.
- Have any serious illness.
- Are taking any medicines (prescription, over the counter, vitamins, or herbal products)

10. Details of manufacturer

Torrent Pharmaceuticals Ltd.

32 No. Middle Camp, NH-10,

East district, Gangtok, Sikkim- 737 135.

11. Details of permission or licence number with date

M/563/2010 issued on 06.12.2021

12. Date of revision

JUN 2025

MARKETED BY

TORRENT PHARMACEUTICALS LTD.

IN/BETACARD 25 mg and 50 mg/JUN 2025/03/PI