SCHEDULING STATUS: **S3**

PROPRIETARY NAME AND DOSAGE FORM:
ADCO ATENOLOL TABLETS 50 mg (TABLET)
ADCO ATENOLOL TABLETS 100 mg (TABLET)

COMPOSITION:
ADCO ATENOLOL TABLETS 50 mg contains 50 mg atenolol
Sugar free.
List of excipients: colloidal silicon dioxide, docusate sodium, gelatine, magnesium stearate, maize starch, methacel ES, microcrystalline cellulose, polyethylene glycol 400, stearic acid, sodium starch glycollate, titanium dioxide and permitted colourant.

ADCO ATENOLOL TABLETS 100 mg contains 100 mg atenolol
Sugar free.
List of excipients: colloidal silicon dioxide, docusate sodium, gelatine, magnesium stearate, maize starch, methacel ES, microcrystalline cellulose, polyethylene glycol 400, stearic acid, sodium starch glycollate, titanium dioxide and permitted colourant.

PHARMACOLOGICAL CLASSIFICATION:
A 5.2 Adrenolytics (sympathicolytics)

PHARMACOLOGICAL ACTION:
Atenolol (**ADCO ATENOLOL TABLETS)** is a beta-adrenoceptor blocking agent, which acts preferentially on beta-adrenergic receptors in the myocardium. It has no intrinsic activity and minimal membrane stabilizing properties. Atenolol does not cross the blood brain barrier to a significant extent.

INDICATIONS:
Management of angina pectoris and hypertension.

CONTRAINDICATIONS:
ADCO ATENOLOL TABLETS should not be used:
1. In the presence of second or third degree heart block.
2. With myocardial depressant agents such as quinidine, procainamide or lignocaine which may enhance the effects of the atenolol.
   With verapamil; neither medicines should be administered within several days of discontinuing the other.
   Particular caution should be exercised with patients suffering from the following: asthma, bronchitis, chronic respiratory diseases, bradycardia less than 50 per minute, peripheral vascular diseases and Raynaud phenomenon.
3. After prolonged fasting.
4. In patients with metabolic acidosis (eg. in diabetes).

5. In cardiac failure, unless or until signs of failure are controlled with digitalis and/or diuretics.

The normal dose of **ADCO ATENOLOL TABLETS** should be reduced in elderly patients or in patients suffering from renal dysfunction.
In the peri-operative period it is generally unwise to reduce the dosage of **ADCO ATENOLOL TABLETS** therapy to which the patient is accustomed, as there may be danger of aggravation of angina pectoris or of hypertension during the surgical period. A patient's normal tachycardiac response to hypovolaemia or blood loss may be obscured during or after surgery by **ADCO ATENOLOL TABLETS** therapy. Particular caution should be taken in this regard.

WARNINGS AND SPECIAL PRECAUTIONS:
Anaesthesia:
The anaesthetist should be made aware of **ADCO ATENOLOL TABLETS** therapy in patients due to undergo general anaesthesia. Anaesthetic agents such as ether, chloroform, cyclopropane and trichloroethylene should be avoided.
It can be dangerous to administer **ADCO ATENOLOL TABLETS** concomitantly with the following medicines:
hypoglycaemic agents, phenothiazines and various anti-arrhythmic agents.
Please note: Such drug reactions can have life-threatening consequences.
ADCO ATENOLOL TABLETS should never be given to patients with phaeochromocytoma without concomitant alpha-adrenoceptor blocking therapy.
Special note: Digitalisation of certain patients receiving long-term **ADCO ATENOLOL TABLETS** therapy can be valuable, particularly those patients in whom congestive cardiac failure is likely to develop. This combination can be considered despite the potentiation of the negative chronotropic effect of the two medicines. Careful control of dosages and of the individual patient's response and notably the pulse rate is essential in this situation.
Abrupt discontinuation of therapy may cause exacerbation of angina pectoris in patients suffering from ischaemic heart disease. Discontinuation of therapy with **ADCO ATENOLOL TABLETS** should be gradual rather than abrupt, and patients should be advised to limit the extent of their physical activity during the period that the medicine is being discontinued.
Treatment with **ADCO ATENOLOL TABLETS** may be associated with exacerbation of peripheral vascular disease, the development of Raynaud phenomenon (due to unopposed arteriolar alpha-sympathetic activity), sexual impotence, hypoglycaemia, skeletal muscle weakness and gastro-intestinal disturbances. Severe peripheral vascular disease and even peripheral gangrene may be precipitated.
Safety during long-term administration has not yet been demonstrated.
Note: Adverse reactions to **ADCO ATENOLOL TABLETS** are more common in patients with renal decompensation; and in patients who receive the drug intravenously.
If **ADCO ATENOLOL TABLETS** and clonidine are given concurrently, the clonidine should not be discontinued until several days after the withdrawal of the **ADCO ATENOLOL TABLETS**, as severe rebound hypertension may occur.

INTERACTIONS:

The effects of other myocardial depressant agents such as quinidine, procainamide or lignocaine may also be enhanced by **ADCO ATENOLOL TABLETS**. The effects of **ADCO ATENOLOL TABLETS** are diminished by beta-adrenergic stimulating agents, the hypotensive effects of **ADCO ATENOLOL TABLETS** may be dangerously reversed and the peripheral vasoconstrictor effects enhanced by alpha-adrenergic stimulating agents such as nor-adrenaline or those with mixed alpha- and beta-adrenergic stimulating properties such as adrenaline. Bradycardia may also occur.

The effects of **ADCO ATENOLOL TABLETS** may be enhanced by adrenergic neuron blocking agents such as guanethidine, bethanidine, or reserpine, and the hypotensive effects by diuretics.

ADCO ATENOLOL TABLETS may enhance some of the cardiac effects of digitalis and diminish others.

PREGNANCY AND LACTATION:

Pregnancy:

The administration of **ADCO ATENOLOL TABLETS** to pregnant mothers shortly before birth or during labour has resulted in new-born infants being born hypotonic, collapsed and hypoglycaemic.

Lactation:

Atenolol is excreted into breast milk. Consult your physician.

DOSAGE AND DIRECTIONS FOR USE:

Angina pectoris:

Most patients with angina pectoris will respond to a dose of 100 mg daily. This is most conveniently administered as a single 100 mg tablet once daily, which may if desired, be given in the form of one 50 mg tablet twice daily. It is unlikely that any additional benefit will be gained by increasing the dose.

Hypertension:

Most patients will respond to a dose of 100 mg once daily. This is most conveniently administered as a single 100 mg tablet once daily. It is unlikely that any additional benefit will be gained by increasing the dosage.

In refractory cases a further reduction of blood pressure may be achieved by combining **ADCO ATENOLOL TABLETS** with other antihypertensive agents. **ADCO ATENOLOL TABLETS** may be combined with a diuretic.

Patients can be transferred to **ADCO ATENOLOL TABLETS** from other antihypertensive treatments.

Caution should be exercised when transferring a patient from clonidine. The withdrawal of clonidine may result in the release of large amounts of catecholamines which may give rise to a hypertensive crisis. If **ADCO ATENOLOL TABLETS** are administered in these circumstances, the unopposed alpha receptor stimulation may potentiate this effect.

SIDE EFFECTS:

Blood and the lymphatic system disorders:

Blood disorders may occur.

Psychiatric disorders:

Depression, hallucinations and disturbances of sleep (sleeplessness, vivid dreams, nightmares).

Nervous system disorders:

The most common side effects are fatigue and dizziness.

Eye disorders:

Dry eyes may occur.

Cardiac disorders:

Bradycardia, congestive heart failure, heart block.

Vascular disorders:

Hypotension, cold extremities, Raynaud phenomenon and paraesthesia.

Respiratory, thoracic and mediastinal disorders:

Bronchospasms may occur particularly in patients suffering from asthma, bronchitis and other chronic pulmonary diseases.

Gastrointestinal disorders:

The most common side effects are nausea, vomiting, diarrhoea.

Skin and subcutaneous tissue disorders:

Skin rashes may occur.

Discontinuance of the drug should be considered if any such reaction is not otherwise explicable.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Overdosage may induce bradycardia and severe hypotension. Bronchospasm and heart failure may be induced in certain individuals. Bradycardia associated with severe hypotension should be treated with atropine 1 to 2 mg intravenously, followed if necessary by a slow infusion of isoprenaline 25 µg or orciprenaline 500 µg intravenously. Bronchospasm should be treated by intravenous aminophylline, and heart failure with digitalis and diuretics.

IDENTIFICATION:

ADCO ATENOLOL TABLETS 50 mg: White, round, film-coated tablets, scored on one side, with a diameter of 8,1 mm.

ADCO ATENOLOL TABLETS 100 mg: Orange, round, film-coated tablets with a diameter of 10,5 mm.

PRESENTATION:

ADCO ATENOLOL TABLETS 50 mg:

Securitainers of 28, 30 and 250 tablets.

Blister packs of 28 and 30 tablets.

ADCO ATENOLOL TABLETS 100 mg:
Securitainers of 28, 30 tablets and 250 tablets.
Blister packs of 28 tablets.

STORAGE INSTRUCTIONS:
Store at or below 25 °C. Protect from light and moisture.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
ADCO ATENOLOL TABLETS 50 mg: W/5.2/115
ADCO ATENOLOL TABLETS 100 mg: W/5.2/116

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