FRONT

Prenolol

PRESENTATION

Tablets containing 25 mg 50 mg or 100 mg of Atenolol BP.

INDICATIONS

i) Hypertension
ii) Angina pectoris
iii) Cardiac arrhythmias
iv) Myocardial infarction. Early and late intervention.

DOSAGE AND ADMINISTRATION

Adults

Hypertension

Most patients respond to 50-100 mg daily given orally 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 “Prenolol” with other antihypertensive agents.

Angina

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

Elderly

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

Children

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

Renal Failure

Since “Prenolol” is excreted via the kidneys dosage should be reduced in cases of severe impairment of renal function. No significant accumulation of “Prenolol” 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 clearange of 15-35 ml/min/1.73 m^2 (equivalent to serum creatinine of 300-600 mcmol/litre) the oral dose should be 50 mg daily. For patients with a creatinine clearance of <15 ml/min/1.73 m^2 (equivalent to serum creatinine of >600 mcmol/litre) the oral dose should be 25 mg daily or 50 mg on alternate 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.

CONTRA-INDICATIONS

“Prenolol” as with other beta-blockers, should not be used in patients with any of the following : known hypersensitivity to the substance ; bradycardia ; cardiogenic shock ; hypotension ; metabolic acidosis ; severe peripheral arterial circulatory disturbances ; second or third degree heart block ; sick sinus syndrome ; untreated phaeochromocytoma ; uncontrolled heart failure.

WARNING/PRECAUTIONS

“Prenolol” as with other beta-blockers :

- although contra-indicated in uncontrolled heart failure (see Contra-indications), 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. “Prenolol” is a beta-1 selective beta-blocker, consequently, its use may be considered although utmost caution must be exercised.
- although contra-indicated in severe peripheral arterial circulatory disturbances (see Contra-indications), 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 modify the tachycardia of hypoglycaemia.
- 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, the dose may be reduced.
- should not be discontinued abruptly in patients suffering from ischaemic heart disease.
- 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 used to treat the allergic reactions.
- may cause an increase in airways resistance in asthmatic patients. “Prenolol” is a beta 1-selective beta-blocker ; consequently its use may be considered although utmost caution must be exercised, if increased airways resistance does occur. “Prenolol” should be discontinued and bronchodilator therapy (e.g. salbutamol) administered if necessary.

INTERACTIONS WITH OTHER MEDICAMENTS AND OTHER FORMS OF INTERACTION

Combined use of beta-blockers and calcium channel blockers with negative inotropic effects e.g. verapamil, diltiazem can lead to an exaggeration of these effects particularly in patients with impaired ventricular function and/or sino-atrial or atrio-ventricular 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 coadministered, 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.

Caution must be exercised when prescribing a beta-blocker with Class 1 antiarrhythmic agents such as disopyramide.

Concomitant use of sympathomimetic agents. e.g. adrenaline, may counteract the effect of beta-blockers. Concomitant use of prostaglandin synthetase inhibiting drugs (e.g. ibuprofen, indomethacin), may decrease the hypotensive effects of beta-blockers.

ขนาดตัด 160 x 220 มม.

BACK

Caution must be exercised when using anaesthetic agents with “Prenolol”. 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.

PREGNANCY AND LACTATION

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

Lactation : There is significant accumulation of “Prenolol” in breast milk. Caution should be exercised when “Prenolol” is administered to a nursing women.

EFFECT ON ABILITY TO DRIVE OR OPERATE MACHINERY

Use is unlikely to result in any impairment of the ability of patients to drive or operate machinery. However it should be taken into account that occasionally dizziness or fatigue may occur.

POSSIBLE ADVERSE DRUG REACTIONS

“Prenolol” 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.

Cardiovascular : bradycardia ; heart failure deterioration ; postural hypotension which may be associated with syncope ; cold extremities, In susceptible patients : precipitation of heart block ; intermittent claudication, Rayaud’s phenomenon.

CNS : confusion ; dizziness ; headache ; mood changes ; nightmares ; psychoses and hallucination ; sleep disturbances of the type noted with other beta-blockers.

Gastrointestinal : dry mouth, gastrointestinal disturbances.

Haematological : purpura ; thrombocytopenia .

Integumentary : alopecia ; dry eyes ; psoriasiform skin reactions ; exacerbation of psoriasis ; skin rashes.

Neurological : paraesthesia.

Respiratory : bronchospasm may occur in patients with bronchial asthma or a history of asthmatic complaints.

Special senses : visual disturbances

Others : fatigue ; 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 reaction.

Bronchospasm can usually be reversed by bronchodilators.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

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 stabilizing activities and as with other beta-blockers, has negative inotropic effects (and is therefore contra-indicated 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.

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.

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

“Prenolol” is compatible with diuretics, other antihypertensive agents and antianginal agents (see Interactions).

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 consistant 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. 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. 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%).

“Prenolol” is effective for at least 24 hours after a single oral daily dose. This simplicity of dosing facilitates compliance by its acceptability to patients.

Storage

Store at or below 25°C

Reference : TIMS annual 1996

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