UROSIN® FILM COATED TABLET

Ingredient(s):
Urosin Film Coated Tablet 50mg
Each tablet contains:
Atenolol 50mg
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Action(s):
1. Atenolol is a beta1-selective (Cardioselective) adrenergic receptor blocking agent without membrane-stabilising and intrinsic sympathomimetic (partial agonist) activities.
2. The action of Atenolol has been demonstrated by:
   a) Reduction in resting and exercise heart rate and cardiac output.
   b) Reduction of systolic and diastolic blood pressure at rest and on exercise.
   c) Inhibition of isoproterenol-induced tachycardia, and
   d) Reduction in reflex orthostatic tachycardia.

Pharmacology (Summary of Pharmacodynamics and Pharmacokinetics):
Atenolol is rapidly but incompletely absorbed from the gastrointestinal tract. 40-50% are excreted in the urine unchanged and the rest are excreted in the feces mostly as unabsorbed drug. In healthy adults, peak plasma of 1-2 µg/ml is achieved at 2-4 hours after 200mg oral administration. Its plasma half-life is 6-7 hours. It is well distributed in most tissues except in brain and CSF. Atenolol crosses the placenta and diffuses to breast milk. About 5-15% are bound to plasma proteins.

Indication(s):
Hypertension, angina pectoris.

Dosage and Administration:
Adults:
a) Hypertension:
   50-100mg per day alone or in conjunction with other antihypertensive agents. The full effects of this dosage will usually be seen within 1-2 weeks. Increasing the dosage more than 100mg is unlikely to produce more beneficial effects.
b) Angina pectoris:
   The dosage for most patients is 50-100mg once a day or in divided doses. Increasing the dosage more than 100mg is unlikely to produce more beneficial effects.

To be dispensed on physician's prescription.

Contraindication(s):
Contraindicated in patients with sinus bradycardia, heart block greater than first degree, cardiogenic shock, and overt cardiac failure. It should not be used in patients with asthma or a history of obstructive airway diseases.

Precaution(s) / Warning(s):
1. Urosin should be given to patients with cardiac failure only when they are fully digitalized and should be done with great caution.
2. It should be used with caution in patients with bronchospastic disease who do not response to, or not tolerate with other antihypertensive treatment.
3. It may mask the symptoms of hyperthyroidism and hypoglycemia and therefore, should be used with caution in these patients.
4. Use in pregnancy and lactation:
   Atenolol crosses the placental barrier and appears in the cord blood. No studies have been performed on the use of Atenolol in the 1st trimester and the possibility of foetal injury cannot be excluded. Atenolol has been used under close supervision for the treatment of hypertension in the 3rd trimester. Administration of Atenolol for longer period to pregnant women in the management of mild to moderate hypertension has been associated with intrauterine growth retardation. The use of Atenolol in women who are, or may are, or may become pregnant, requires that the anticipated benefit be weighed against the possible risks, particularly in the 1st and 2nd trimesters. There is significant accumulation of Atenolol in breast milk. Caution should be exercised when Atenolol is administered to a nursing mother.

Drug Interaction(s):
The effects of salbutamol and isoprenaline on the bronchi are not impaired by Atenolol. Atenolol can therefore be used in patients with obstructive airway diseases provided appropriate care is taken.
Where ventricular function is impaired, β-blockers and calcium antagonists of the verapamil type should be combined only with care. Such combinations must be avoided in conduction disorders.
Care is needed when β-blockers are combined with class I antiarrhythmic agents, e.g. disopyramide. Care is also required when a change is made from clonidine to Atenolol. If clonidine is given together with a β-blocker and treatment is discontinued, the β-blocker should be discontinued a few days before the gradual withdrawal of clonidine.
It is not advisable to discontinue a β-blocker before anaesthesia. Certain reactions during anaesthesia are altered by β-blockade. The anaesthetist must therefore be informed if a patient being treated with Atenolol has to have a general anaesthetic. Vagal stimulation can be counteracted by atropine 1-2mg by IV.
In some circumstances, Atenolol can potentiate the hypoglycaemic effects of insulin.

Side Effect(s) / Adverse Reaction(s):
Bradycardia, cold extremities, postural hypotension, dizziness, vertigo, nausea, diarrhea, fatigue, skin rash, and dry eyes.

Symptoms and Treatment for Overdosage, and Antidote(s):
Excessive bradycardia may be countered by atropine 1-2mg intravenously, followed if necessary, by a bolus dose of glucagon 10mg intravenously. If required this may be repeated or followed by an intravenous infusion of glucagon 1-10mg/hour depending on response.
If no response to glucagons or glucagon is unavailable, dobutamine 2.5 to 10mcg/kg/minute by intravenous infusion may be given.
Any risk of hypotension occurring followed the use of beta-adrenoceptor agonists will be reduced by the used of the more selective agents, e.g. dobutamine.

Storage Condition(s):
Keep in a tight container. Store at temperature below 30ºC. Protect from light and moisture.

Shelf-Life:
3 years from the date of manufacture.

Product Description and Packing:
Urosin Film Coated Tablet 50mg:
A white round film coated tablet and one side with the mark "50".
Blister packing of 7's x 2, 10's x 10 and 10's x 100.
Plastic bottle of 28's
Plastic bottle of 1000's.

Urosin Film Coated Tablet 100mg:
A white color film coated tablet, one side impressed with the mark "Y S".

Plastic bottle of 500's, 1000's and 1200's.
Blister packing of 10's x 10 and 10's x 50.
(Not all presentation may be available locally).

Y. S. P.®

Manufacturer and Product Registration Holder:
Y.S.P. INDUSTRIES (M) SDN. BHD. (199001001034)
Lot 3, 5 & 7, Jalan P/7, Section 13,
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Product Registrant and Importer:
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