Alphalok®

Prazosin Hydrochloride USP

Description: Prazosin is a lipid-soluble alpha-1- adrenergic receptor antagonist that crosses the blood-brain barrier and decreases the sympathetic outflow in the brain.

Mode of Action: Prazosin is an alpha-1 adrenergic receptor blocker. By blocking alpha-1 receptors on muscle cells that surround blood vessels, prazosin causes vasodilation of the blood vessels, and decreases the resistance of blood flow.

Composition:
Alphalok® 1 mg tablet: Each tablet contains Prazosin 1 mg.
Alphalok® 2 mg tablet: Each tablet contains Prazosin 2 mg.
Alphalok® XR 2.5 mg tablet: Each extended release tablet contains Prazosin 2.5 mg.
Alphalok® XR 5 mg tablet: Each extended release tablet contains Prazosin 5 mg.

Pharmacokinetics:
Absorption: The time of peak concentration occurs between 1 and 3 hours after oral administration.
Absorption is not influenced by the presence of food in the digestive tract. The systemic bioavailability of prazosin ranges from 43.5 to 69.3% (mean 56.9%).
Distribution: The volume of distribution for prazosin is 25–30 L. Prazosin is highly (92 to 97%) bound to human plasma proteins.
Metabolism and Elimination: Prazosin is extensively metabolized by the liver. This occurs through demethylation and conjugation. The plasma half-life is about 2-3 hours. Prazosin mainly excreted in the bile and the feces.

Indication: Prazosin is indicated for the treatment of hypertension. It is also used in the treatment of Raynaud's disease and benign prostatic hyperplasia.

Dosage & administration: Dosage should be individualized depending on patient tolerance and response. Initial Dose 1 mg two or three times a day. Therapy for hypertension should be initiated with Prazosin extended release 2.5 mg once daily. Prazosin extended release 5 mg is not for initial dosing. Dosage may be increased slowly, in general over a 7 to 14 day period, depending on the response to each dose level. Doses above 20 mg once daily have not been studied. Maintenance Dose: Dosage may be slowly increased to a total daily dose of 20 mg given in divided doses. Use with Other Drugs When adding a diuretic or other antihypertensive drug, the dose of Prazosin should be reduced to 1 mg or 2 mg three times a day and re-titration then carried out.

Contraindication: It is not given in patients with known sensitivity to quinolones, prazosin, or any of the inert ingredients.

Side effects: Side effects include Headache, drowsiness, tiredness, weakness, blurred vision, nausea, vomiting, diarrhea, or constipation etc.

Use in pregnancy & lactation: Pregnancy Category C. Prazosin should be used during pregnancy only if in the opinion of the physician the potential benefit outweighs potential risk to mother and child. Lactation: Prazosin has been shown to be excreted in small amounts in human milk. Caution should be exercised when Prazosin is administered to a nursing woman.

Precautions: Patients with moderate to severe grades of renal impairment have, in some cases, responded to smaller than usual doses of prazosin. Therefore, that treatment with prazosin should be initiated at 0.5 mg daily and must be caution with increase in dose. Prazosin may cause syncope with sudden loss of consciousness. In most cases, this is believed to be due to an excessive postural hypotensive effect, although occasionally the syncopal episode has been preceded by a bout of severe tachycardia with heart rates of 120–160 beats per minute. Syncopal episodes can be minimized by limiting the initial dose of the drug to 1 mg, by subsequently increasing the dosage slowly. The 2 and 5 mg tablet are not indicated for initial therapy.

Drug interactions: Prazosin has been administered without any adverse drug interaction in clinical experience to date with the following: Digitalis and digoxin, insulin, chlorpropamide, phenformin, tolazamide and tolbutamide, chlordiazepoxide, diazepam and phenobarbital, allopurinol, colchicine and probenecid, procainamide, propranolol and quinidine, propoxyphene, aspirin, indomethacin and phenylbutazone.

Overdose: Accidental ingestion of at least 50 mg of Prazosin in a two year old child resulted in profound drowsiness and depressed reflexes. No decrease in blood pressure was noted. Recovery was uneventful. Should over dosage lead to hypotension, so support of the cardiovascular system is of first importance. Restoration of blood pressure and normalization of heart rate may be accomplished by keeping the patient in the supine position. If this measure is inadequate, shock should first be treated with volume expanders. If necessary, vasopressors should then be used. Renal function should be monitored and supported as needed. Laboratory data indicate Prazosin is not dialysable because it is protein bound.

Storage: Keep out of reach of children. Store in a dry place, below 25° C temperature and protected from light.

Packaging: Alphalok® 1 mg tablet: Each box contains 14x3 tablets in blister pack.
Alphalok® 2 mg tablet: Each box contains 14x3 tablets in blister pack.
Alphalok® XR 2.5 mg tablet: Each box contains 14x2 tablets in blister pack.
Alphalok® XR 5 mg tablet: Each box contains 14x2 tablets in blister pack.

Opsonin Pharma
Ideas for healthcare

Manufactured by
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