SPMC
DILTIAZEM HYDROCHLORIDE TABLETS USP 60 mg
DILTIAZEM HYDROCHLORIDE TABLETS USP 30 mg

PRESENTATION:

Diltiazem Hydrochloride Tablets USP 60 mg
Pack of 1000 tablets.
Blister pack of 10X20 (200 tablets)
Each light green circular, biconvex film coated tablets of 7.00 mm in diameter. Each tablet contains 60 mg Diltiazem Hydrochloride.

Diltiazem Hydrochloride Tablets USP 30 mg
Bulk Pack of 500/1000 tablets.
Blister pack of 10X20 (200 tablets)
Each pink circular, biconvex film coated tablets of 6.50 mm in diameter, with score mark on one side and SPC, SPMC letters on the other side. Each tablet contains 30 mg Diltiazem Hydrochloride.

INDICATIONS AND DOSE:
Prophylaxis and treatment of angina
Adult: Initially 60 mg 3 times a day, adjusted according to response; maximum 360 mg per day
Elderly: Initially 60 mg twice daily, adjusted according To response; maximum 360 mg per day
Mild to moderate hypertension
Adult: 120 mg twice daily, dose form not appropriate for initial dose titration
Angina
Adult: Initially 90 mg twice daily; increased if necessary, To 180 mg twice daily, dose form not appropriate for Initial dose titration in the elderly
Angina | Mild to moderate hypertension
Adult: Initially 240 mg once daily, increased if Necessary, to 300 mg once daily
Elderly: Initially 120 mg once daily, increased if Necessary, up to 300 mg once daily
Angina | Mild to moderate hypertension
Adult: Initially 90 mg twice daily; increased if necessary, To 120–180 mg twice daily
Angina | Mild to moderate hypertension
Adult: Initially 240 mg once daily; increased if Necessary, to 300 mg once daily, dose form not appropriate for initial dose titration in the elderly
Angina | Mild to moderate hypertension
Adult: Initially 90 mg twice daily; increased if necessary, To 180 mg twice daily
Elderly: Initially 60 mg twice daily; increased if Necessary, to 90 mg twice daily
Angina | Mild to moderate hypertension
Adult: Initially 180 mg once daily; increased if Necessary, to 360 mg once daily
Elderly: Initially 120 mg once daily; increased if necessary, to 360 mg once daily
Mild to moderate hypertension
Adult: Initially 90–120 mg twice daily; increased if necessary, to 360 mg daily in divided doses
Elderly: Initially 120 mg once daily; increased if necessary, to 120 mg twice daily

CONTRA-INDICATIONS:
With systemic use Acute porphyrias, left ventricular failure with pulmonary congestion. second- or third-degree
AV block (unless pacemaker fitted). severe bradycardia. sick sinus syndrome

CONTRA-INDICATIONS, FURTHER INFORMATION
Systemic absorption following rectal use is unknown, therefore consider the possibility of contra-indications listed for systemic use.

HEPATIC IMPAIRMENT:
Dose adjustments; With systemic use Reduce dose.

SIDE EFFECTS:
Common or very common **Cardiac** conduction disorders. Constipation. Gastrointestinal discomfort. Malaise
Uncommon Arrhythmias. Diarrhoea, Insomnia. Nervousness. Postural hypotension Dry mouth Angioedema. Cardiac arrest. Congestive heart failure. Depression. Extrapyramidal Symptoms. Fever. Gynecomastia. Hepatitis. Hyperglycemia. Hyperhidrosis. Mood altered. Photosensitivity reaction. Severe cutaneous adverse reactions (SCARs). Thrombocytopenia. Vasculitis

SIDE-EFFECTS, FURTHER INFORMATION :
Systemic absorption following rectal use is unknown; therefore, consider the possibility of side-effects listed for oral use. Overdose With oral use in overdose, diltiazem has a profound cardiac depressant effect causing hypotension and arrhythmias, including complete heart block and asystole.

BREAST-FEEDING:
As this drug is excreted in breast milk, breast-feeding while taking diltiazem is contraindicated
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PREGNANCY:
There are very limited data from the use of diltiazem in pregnant patients. Diltiazem has been shown to have reproductive toxicity in certain animal species (rat, mice, rabbit). Diltiazem is therefore not recommended during pregnancy, as well as in women of childbearing potential not using effective contraception

CAUTIONS:
With systemic use Bradycardia (avoid if severe). first degree AV block. heart failure. prolonged PR interval. significantly impaired left ventricular function

CAUTIONS, FURTHER INFORMATION
Systemic absorption following rectal use is unknown, therefore consider the possibility of cautions listed for systemic use.

INTERACTIONS:
ACE inhibitors: enhanced hypotensive effect when calcium- channel blockers given with ACE inhibitor. Alcohol: Enhance hypotensive effect Aldesleukin: enhance hypotensive effect Alpha-blockers: enhance hyposensitivity, also increased risk of first-dose hypotension with post- synaptic alpha blockers such as prazosin. Analgesic: hypotensive effect of calcium-channel blockers antagonized by NSAID; diltiazem inhibit metabolism of alfentanil.
Angiotensin–II receptor antagonist: enhance hypotensive effect Antibacterial: metabolism of calcium- channel blockers possibly inhibited by clarithromycin, erythromycin and telithromycin; metabolism of diltiazem accelerated by rifampicin. Beta-blockers: enhance hypotensive effect; increased risk of AV block and bradycardia when diltiazem given with beta-blockers
Vasodilator Antihypertensive: enhanced hypotensive effect when calcium-channel blockers given with hydralazine, minoxidil or sodium nitroprusside

OVERDOSE:
Symptoms The clinical effects of acute overdose can involve pronounced hypotension leading to collapse and acute kidney injury, sinus bradycardia with or without isorhythmic dissociation, sinus arrest, atrioventricular conduction disturbances and cardiac arrest.

Treatment, in a hospital setting, will include gastric lavage and/or osmotic diuresis. Conduction disturbances may be managed by temporary cardiac pacing. Proposed corrective treatments: atropine, vasopressors, inotropic agents, glucagon and calcium gluconate infusion.

STORAGE:
Keep tightly closed in a cool dry place. Protect from light. Keep all medicines away from children. Store below 30^0 C.

Manufactured by:
State Pharmaceuticals Manufacturing Corporation
No. 11, Sir John Kotalawala Mawatha, Kandawala Estate,
Ratmalana, Sri Lanka.