CLONIDINE HYDROCHLORIDE
CATAPIN
75 mcg Tablet
Centrally Acting Antiadrenergic Agent

FORMULATION:
Each tablet contains:
Clonidine Hydrochloride.....75 mcg

PRODUCT DESCRIPTION:
Catapin is a white to off-white, round, flat beveled edge tablet, plain on one side and bisected on the other side.

PHARMACOLOGY:
Clonidine stimulates alpha-adrenoceptors in the brain stem. This action results in reduced sympathetic outflow from the central nervous system and decreases in peripheral resistance, renal vascular resistance, heart rate, and blood pressure. Clonidine hydrochloride tablets act relatively rapidly. The patient's blood pressure declines within 30 to 60 minutes after an oral dose, the maximum decrease occurring within 2 to 4 hours. Renal blood flow and glomerular filtration rate remain essentially unchanged. Normal postural reflexes are intact; therefore, orthostatic symptoms are mild and infrequent.

PHARMACOKINETICS:
Following oral administration, clonidine is well absorbed from the gastrointestinal tract, with peak plasma concentrations observed after about 3 to 5 hours. About 50% of an administered dose is metabolized in the liver. It is excreted in the urine as unchanged drug metabolites, 40% to 60% of an oral dose being excreted in 24 hours as unchanged drug; about 20% of a dose is excreted in the faeces, probably via enterohepatic circulation. The elimination half-life has been variously reported to range between 6 and 24 hours, extended up to 41 hours in patients with impaired renal function.

INDICATIONS:
Used in the management of hypertension including hypertensive crisis.

DOSAGE AND ADMINISTRATION:
Hypertension: Usual initial dose is 50 to 100 mcg three times daily, increased every second or third day according to the response of the patient; the usual maintenance dose is 300 mcg to 1200 mcg daily but the dose of 1800 mcg or more daily may sometimes be required, or as prescribed by the physician.

Prophylaxis of migraine or recurrent vascular headaches and treatment of menopausal flushing, the dose is 50 mcg twice daily increased, if there is no remission after 2 weeks, to 75 mcg twice daily.

CONTRAINDICATIONS:
Clonidine hydrochloride tablets should not be used in patients with known hypersensitivity to clonidine.

PRECAUTIONS:
Diseases affecting rhythmic & AV conduction system of the heart; renal failure. Impairment of ability to drive or operate machinery. Sudden discontinuation may cause rebound hypertension, sometimes severe.

WARNINGS:
Rebound hypertension may occur after abrupt discontinuation; taper dose over 5-7 days before stopping the drug. Causes drowsiness in the elderly.

PREGNANCY AND LACTATION:
Pregnancy: There are limited amount of data from the use of clonidine in pregnant women. During pregnancy clonidine HCl, as any drug, should only be administered if clearly needed. Careful monitoring of mother and child is recommended. Clonidine passes the placental barrier and may lower the heartrate of fetus. There is no adequate experience regarding the long-term effects of prenatal exposure. During pregnancy the oral forms of clonidine should be preferred.
Lactation: Clonidine is excreted in human milk. However, there is insufficient information on the effects on newborns. The use of clonidine HCl is therefore not recommended during breast feeding.

DRUG INTERACTIONS:
Clonidine may potentiate the CNS-depressive effects of alcohol, barbiturates or other sedating drugs. If a patient receiving clonidine hydrochloride is also taking tricylic antidepressants, the hypotensive effect of clonidine may be reduced, necessitating an increase in the clonidine dose.

ADVERSE EFFECTS:
Dry mouth, dizziness, drowsiness, constipation, sedation, fatigue, fever, headache, pallor, weakness, and withdrawal syndrome. Also reported were a weakly positive Coombs' test and increased sensitivity to alcohol.

OVERDOSE AND TREATMENT:
Symptoms: Clonidine has a wide therapeutic range. Manifestations of intoxication are due to generalized sympathetic depression and include papillary constriction, lethargy, bradycardia, hypotension, hypothermia, somnolence including coma, respiratory depression including apnea. Paradoxic hypertension caused by stimulation of peripheral alpha-1-receptors may occur.
Treatment: Careful monitoring and symptomatic measures.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

AVAILABILITY:
Clear PVDC / Alu Blister Pack x 10's (Box of 100's)

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

ADR REPORTING STATEMENT:
"For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph".
Seek medical attention immediately at the first sign of any adverse drug reaction.

REGISTRATION NUMBER:
DRP-6744

DATE OF RENEWAL OF AUTHORIZATION:
September 1, 2021

DATE OF INSERT REVISION:
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