Vidol® (Tablets)

1292
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Carvedilol

Beta-adrenoceptor Antagonist
Antihypertensive

VIDOL® 6.25MG TABLETS (FILM COATED)
VIDOL® 12.5MG TABLETS (FILM COATED)
VIDOL® 25MG TABLETS (FILM COATED)

PRESENTATION:
Vidol® 6.25mg Tablets : Light yellow, circular, biconvex film coated tablet embossed 'C' on one side and a breakline on the other side. Each film coated tablet contains: Carvedilol 6.25mg, Lactose and other excipients.
Vidol® 12.5mg Tablets : Light orange, circular, biconvex film coated tablet embossed 'C' on one side and a breakline on the other side. Each film coated tablet contains: Carvedilol 12.5mg, Lactose and other excipients.
Vidol® 25mg Tablets : White, circular, biconvex film coated tablet embossed 'C' on one side and a breakline on the other side. Each film coated tablet contains: Carvedilol 25mg, Lactose and other excipients.

CLINICAL PHARMACOLOGY:
Carvedilol is a nonselective β-adrenergic blocking agent with selective α_1-adrenergic blocking activity. The principal physiologic action of carvedilol is to competitively block adrenergic stimulation of β-receptors within the myocardium (β_1-receptors) and within bronchial and vascular smooth muscle (β_2 receptors), and to a lesser extent α_1-receptors within vascular smooth muscle. The β_1 antagonist activity of carvedilol is similar to that of propranolol and greater than that of labetalol, and the duration of carvedilol's effect is longer than those of labetalol and propranolol. Studies in animals indicate that the drug may exert an antioxidant effect on the myocardium and an antiproliferative effect on intimal tissue. Carvedilol does not exhibit intrinsic sympathomimetic (β_1-agonist) activity and possesses only weak membrane-stabilizing (local anesthetic) activity.

Pharmacokinetics:
Carvedilol is well absorbed from the gastrointestinal tract but is subject to considerable first-pass metabolism in the liver; the absolute bioavailability is about 25%. Peak plasma concentrations occur in 1 to 2 hours after an oral dose. It has high lipid solubility. Carvedilol is more than 98% bound to plasma proteins. It is extensively metabolised in the liver, primarily by the cytochrome P450 isoenzymes CYP2D6 and CYP2C9, and the metabolites are excreted mainly in the bile. The elimination half-life is about 6 to 10 hours. Carvedilol has been shown to accumulate in breast milk in animals.

USES:
Vidol® is used in the management of hypertension and angina pectoris and as an adjunct to standard therapy in symptomatic heart failure. It is also used to reduce mortality in patients with left ventricular dysfunction following myocardial infarction.

DOSAGE AND ADMINISTRATION:
Hypertension: Initial dose, 12.5mg once daily, increased after 2 days to 25mg once daily. Alternatively, an initial dose of 6.25mg twice daily increased after one to two weeks to 12.5mg twice daily. The dose may be increased further, if necessary, at intervals of at least two weeks, to 50mg once daily or in divided doses. A dose of 12.5mg once daily may be adequate for elderly patients.
Angina pectoris: Initial dose, 12.5mg twice daily, increased after 2 days to 25mg twice daily.
Heart failure: Initial dose, 3.125mg twice daily given with food to reduce the risk of hypotension. If tolerated, the dose should be doubled after 2 weeks to 6.25mg twice daily and then increased gradually at intervals of not less than two weeks, to the maximum dose tolerated. The dose should not exceed 25mg twice daily in patients with severe heart failure or in those weighing less than 85kg, or 50mg twice daily in patients with mild to moderate heart failure weighing more than 85kg.

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CONTRA-INDICATIONS AND WARNINGS:

Precautions:

Carvedilol may cause bradycardia; dosage should be reduced if heart rate is less than 55 beats/minute. May cause hypotension, postural hypotension, or syncope. Risk is highest in first 30 days of therapy in patients with congestive heart failure. To decrease risk of orthostatic hypotension, administer with food and strictly adhere to the usual starting dose . In patients with pheochromocytoma, an α-adrenergic blocking agent should be administered before using a β-adrenergic blocking agent.

Adverse Effects:

The most frequent and serious adverse effects are related to their beta-adrenergic blocking activity. Among the most serious adverse effects are heart failure,heart block, and bronchospasm. Cardiovascular effects include bradycardia and hypotension; heart failure or heart block may be precipitated in patients with underlying cardiac disorders.CNS effects include headache, depression, dizziness, hallucinations, confusion, and sleep disturbances. Fatigue, paraesthesia, peripheral neuropathy, arthalgia, and myopathies, including muscle cramps have been reported. Adverse gastrointestinal effects include nausea and vomiting, diarrhoea, constipation,and abdorminal cramping.

Interactions:

Both pharmacodynamic and pharmacokinetic interactions have been reported with β-blockers. Like other β-blokers Carvedilol may enhance the blood pressure reduction brought about by other drugs whose therapeutic or side effect profile includes the lowering of blood pressure. Simultaneous use of nifedipine and carvedilol can result in an exaggerated fall in blood pressure. The effect of insulin or oral hypoglycemic agents may be enhanced. The signs and symptoms of hypoglycemia, especially tachycardia , may be masked or attenuated. Regular blood glucose determinations are therefore required in diabetics.
Drugs that induce oxidating metabolism (e.g. rifampicin) reduce plasma levels of carvedilol.
Simultaneous administration of carvedilol and digoxin can lead to an increase in digoxin levels.

Pregnancy and breastfeeding:

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

PHARMACEUTICAL PRECAUTIONS:

Store in a dry place below 30ºC. Protect from light. Keep all medicines out of the reach of children.

LEGAL CATEGORY:

Prescription Only Medicine (POM)

®Regd. TM

COSMOS

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