**Composition : Cavelon-6.25 :** Each tablet contains Carvedilol USP 6.25mg.

**Cavelon-12.5 :** Each tablet contains Carvedilol USP 12.5mg.

**Description : Cavelon** is a non-selective  $\beta$ -adrenergic blocking agent with  $\alpha_1$ -blocking activity.

**Pharmacology : Cavelon** is rapidly & extensively absorbed following oral administration, with absolute bioavailability of approximately 25% to 35% due to a significant degree of first-pass metabolism. Following oral administration, the apparent mean terminal elimination half-life of **Cavelon** generally ranges from 7 to 10 hours. Plasma concentrations achieved are proportional to the oral dose administered.

**Indications : Cavelon** is indicated for the management of essential hypertension. It can be used alone or in combination with other antihypertensive agents, especially thiazide type diuretics.

**Dosage & administration :** Hypertension : Take with food to slow the rate of absorption and reduce the incidence of orthostatic effects. The recommended starting dose is 6.25mg twice daily. If this dose is tolerated, using standing systolic pressure measured ~ 1 hour after dosing as a guide, maintain the dose for 7 to 14 days, and then increase to 12.5mg twice daily, if needed, based on through blood pressure, again using standing systolic pressure 1 hour after dosing as a guide for tolerance. This dose should also be maintained for 7 to 14 days and can then be adjusted upward to 25mg twice daily if tolerated and needed.

Congestive heart failure (CHF) : The recommended starting dose of carvedilol is 3.125mg twice/day for 2 weeks. If this dose is tolerated, it can then be increased to 6.25mg twice/day. Dosing should then be doubled every 2 weeks to the highest level tolerated by the patients. At initiation of each new dose, observe patients for signs of dizziness or lightheadedness for 1 hour. The maximum recommended dose is 25mg twice/day in patients weighing <85 kg and 50mg twice/day in patients weighing >85 kg. Or, as directed by the registered physician.

**Contraindications : Cavelon** is contraindicated in patients with asthma, chronic obstructive pulmonary disease (COPD) with a bronchospasmatic component, clinically manifest liver dysfunction, second or third degree heart block, severe bradycardia, cardiogenic shock, uncontrolled heart failure, obstructive airways disease, sick sinus syndrome, hypersensitivity to Carvedilol.



**Precautions :** Since **Cavelon** has  $\beta$ -blocking activity, it should not be discontinued abruptly, particularly in patients with ischaemic heart disease. Care should be taken in the administration of **Cavelon** to patients with diabetes mellitus, as the early signs and symptoms of acute hypoglycaemia may be masked or attenuated.

**Side effects : Cavelon** is usually well tolerated. Symptomatic postural hypotension mainly on the initiation of therapy or when increasing the dose may occur but the incidence is minimised when the drug is used as recommended dose. Dizziness, headache, fatigue, gastrointestinal upset and bradycardia have been observed.

**Use in pregnancy and lactation : Cavelon** should be used during pregnancy only if the potential benefit justifies the potential risk. Breast-feeding is not recommended during administration of **Cavelon**.

**Use in Child :** Safety and effectiveness in children have not been established.

**Drug Interactions :** As with other agents with betablocking activity, Carvedilol may potentiate the effect of other concomitantly administered drugs that are antihypertensive in action or have hypotension as part of their adverse effect profile. Following concomitant administration of Carvedilol and digoxin, concentration of digoxin were increased in hypertensive patients. Increased monitoring of digoxin levels is recommended when initiating, adjusting or discontinuing Carvedilol. Concomitant administration of Carvedilol and cardiac glycosides may prolong AV conduction time.

Overdose : There is no data available.

**Storage :** Store below 30°C in a dry place.

**Packing : Cavelon-6.25 :** Each box contains 5 x 10's tablets in blister pack.

**Cavelon-12.5**: Each box contains 5 x 10's tablets in blister pack.