

CHOLESTRAN

Powder

Antihypercholesterolemic

Antipruritic - Antidiarrheal

1- **Company Name:** Pharco Pharmaceuticals

2- **Trade Name:** Cholestran Powder

3- **Generic Name:** Cholestyramine

4- **Composition:**

Cholestyramine 4 gm/sachet

5- **Pharmaceutical Form:** Powder

6- **Pharmacological Action:**

Cholestyramine, the active ingredient of **Cholestran**, is the chloride salt of a basic anion-exchange resin.

In the small intestine, cholestyramine binds bile acids forming an insoluble complex which prevents intestinal reabsorption of bile acids and promotes their fecal excretion. As a result, the rate of hepatic conversion of cholesterol to bile acids is increased causing depletion of the hepatocytes cholesterol contents with a subsequent increase in hepatic low-density lipoprotein (LDL) receptor activity. These changes enhance the clearance of LDL from plasma and, in turn, reduce elevated plasma cholesterol levels. Cholestran is also of therapeutic value for the relief of pruritus, due to partial biliary obstruction, and diarrhea caused by increased concentrations of bile acids in the colon.

Cholestran, in addition, is capable of binding oxalic acid and other negatively charged molecules within the lumen of the GIT, a property which broadens the therapeutic spectrum of Cholestran.

7- **Pharmacokinetics:**

Cholestyramine is not absorbed from the digestive tract.

8- **Indications:**

Cholestran is used for:

1- Primary prevention of coronary heart disease in men between 35 and 59 years of age and with primary hypercholesterolaemia who have not responded to diet and other appropriate measures.

2- Reduction of plasma cholesterol in hypercholesterolaemia, particularly in those patients who have been diagnosed as Fredrickson's Type II (high plasma cholesterol with normal or slightly elevated triglycerides).

3- Relief of pruritus associated with partial biliary obstruction and primary biliary cirrhosis.

4- Relief of diarrhea associated with ileal resection, Crohn's disease, vagotomy and diabetic vagal neuropathy.

5- Management of radiation-induced diarrhea.

9- **Dosages:**

Adults:

1- For primary prevention of coronary heart disease and to reduce cholesterol: After initial introduction over a three to four week period, 3 to 6 Cholestran sachets per day, administered either as a single daily dose or in divided doses up to four times daily, according to dosage requirements and patient acceptability.

Dosage may be modified according to response and can be increased to 9 sachets per day if necessary. Occasional slight gastro-intestinal upsets, e.g. constipation, may occur on starting Cholestran.

These usually pass with continued usage of Cholestran and are minimised by starting therapy gradually. (see Table below)

Final dose required	Week 1	Week 2	Week 3	Week 4
	Sachets per day			
3	1	2	3	3
4	1	2	3	4
6	1	2	3	6

2- To relieve pruritus: One or two sachets daily are usually sufficient.

3- To relieve diarrhea: As for reduction of cholesterol but it may be possible to reduce this dosage. In all patients presenting with diarrhoea induced by bile acid malabsorption, if a response is not seen within 3 days, then alternative therapy should be initiated.

Children:

Children 6 – 12 years: 80 mg/kg body weight, 3 times daily.

Infants and children under 6 years: the dosage has not been established.

Elderly:

No dosage adjustment is necessary.

Preparation and administration:

Cholestran should not be taken in dry form. The dose is prepared by adding the contents of one sachet to a glass of water (about 150 ml). Allow to stand without stirring for 1-2 minutes, then stir and mix thoroughly to obtain a homogeneous suspension. **Cholestran** may also be taken with juices or other fluids.

10- **Contraindications**

In patients with complete biliary obstruction, since **Cholestran** cannot be effective where bile is not secreted into the intestine.

11- **Side effects:**

Since **Cholestran** may interfere with the absorption of fat soluble vitamins, the diet may require supplementation with Vitamins A, D and K during prolonged high dose administration. Chronic use of **Cholestran** may be associated with increased bleeding tendency due to hypoprothrombinaemia associated with Vitamin K deficiency. This will usually respond promptly to parenteral Vitamin K administration; recurrences can be prevented by oral administration of Vitamin K.

Hyperchloraemic acidosis has occasionally been reported following the prolonged use of anion exchange resins.

Gastro-intestinal side effects are those most frequently reported. The principal complaint is constipation which may be controlled with the usual remedies, and frequently disappears on continued usage of **Cholestran**. Large doses of **Cholestran** can cause diarrhoea.

12- **Drug Interactions:**

Cholestran may delay or reduce the absorption of certain drugs (such as digitalis, tetracycline, chlorothiazide, warfarin and thyroxine). The response to concomitant medication should be closely monitored and appropriate adjustments made if necessary.

Cholestran may interfere with the pharmacokinetics of drugs that undergo enterohepatic recirculation.

Patients should take other drugs at least one hour before or 4-6 hours after **Cholestran** to minimize possible interference with their absorption.

13- **Pregnancy and lactation:**

The safety of cholestyramine in pregnancy and lactation has not been established.

14- **Warnings and Precautions:**

Reduction of serum folate concentrations has been reported in children with familial

Hypercholesterolaemia.

Supplementation with folic acid should be considered in these cases.

15- **Packing:**

A box containing 12 sachets.

16- **Storage:**

Store below 30° C, in dry place.

Keep out of the reach of children.

THIS MEDICAMENT

- Is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

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