RESINCOLESTIRAMINA

Cholestyramine

RESINCOLESTIRAMINA Powder
RESINCOLESTIRAMINA is an insoluble salt of an anionic exchange resin, with a high capacity for absorption of bile acids in the intestine.
Bile acids are produced in the liver by cholesterol oxidation.
Due to this fact, when they are absorbed, it becomes necessary to synthesise them from the body's cholesterol thereby lowering cholesterol levels in the body.
In order to increase the drug's efficacy, a low-cholesterol diet should be given. Due to the high absorption capacity of RESINCOLESTIRAMINA for bile acids, it is used in the treatment of pruritus secondary to obstructive jaundice, both entero- and extrahepatic.

DESCRIPTION
White sachets of a complex material of polyethylene-aluminium-polyethylene-paper which contains flavoured powder.

COMPOSITION PER SACHET:
Cholestyramine (anhydrous) 4g
Excipients q.s.
Strawberry flavour

INDICATIONS
RESINCOLESTIRAMINA is indicated as adjunctive therapy in hypercholesterolaemia and as an adjunct for the relief of intractable diarrhoea and for the relief of pruritus secondary to biliary stasis.

CONTRAINDICATIONS
It is contraindicated in patients with complete biliary obstruction and in those individuals who have shown hypersensitivity to any of its components.

SIDE-EFFECTS
The most common side-effect of cholestyramine is constipation; faecal impaction may develop and haemorrhoids may be aggravated. Other gastro-intestinal side-effects, including abdominal discomfort or pain, heartburn, flatulence, nausea, vomiting, and diarrhoea, may also occur.
Cholestyramine in high doses may cause steatorrhoea by interfering with the absorption of fats from the gastro-intestinal tract and therefore decreased absorption of fat-soluble vitamins, such as vitamins A, D, and K, may occur. Chronic administration of cholestyramine may thus result in an increased bleeding tendency due to hypoprothrombinaemia associated with vitamin K deficiency or it may lead to osteoporosis due to impaired calcium and vitamin D absorption.
Due to the fact that cholestyramine is the chloride form of an anion-exchange resin, prolonged use may produce hyperchloraemic acidosis, particularly in children.
Skin rashes and pruritus of the tongue, skin and perianal region have occasionally occurred.

INCOMPATIBILITIES
Due to the intestinal absorption properties of RESINCOLESTIRAMINA, no drugs should be given orally for one hour before and 4 hours after ingestion of the resin.

DRUG INTERACTIONS
RESINCOLESTIRAMINA may delay or reduce the absorption of concomitant oral medication such as: phenylbutazone, warfarin, chlorothiazide (acidic) or propranolol (basic), as well as tetracycline, penicillin G, phenobarbital, thyroid and thyroxine preparations, and digitalis. The discontinuance of RESINCOLESTIRAMINA, could pose a hazard to health if a potentially toxic drug such as digitalis has been titrated to a maintenance level while the patient was taking RESINCOLESTIRAMINA.
RESINCOLESTIRAMINA may prevent absorption of fat soluble vitamins such as A, D and K. When RESINCOLESTIRAMINA is given for long periods of time, concomitant supplementation with water-soluble or parenteral form of vitamins A and D should be considered.

DOSAGE
Adults: 12-16 g which is equivalent to one sachet (4 g) three or four times daily.
Children: 4-8 g which is equivalent to one sachet (4 g) one or two times daily.
Subsequent adjustment should be made according to clinical response or laboratory results and the benefit/risk ratio.
It is recommended that RESINCOLESTIRAMINA be given before meals, dissolved in 1/2 glass of milk or fruit juice. In treatment of hypercholesterolaemia and pruritus, it is preferable to administer the total daily dose in two doses, one before breakfast and one before the evening meal.

PRECAUTIONS/WARNINGS
RESINCOLESTIRAMINA should not be taken in its dry form. It should be administered as a suspension in water or a flavoured vehicle to minimise the risk of oesophageal obstruction.
Cholestyramine should not be used in patients with complete biliary obstruction as it is unlikely to be effective.
Because of the risk of vitamin deficiencies, supplements of vitamins A and D and possible K should be given in a water-miscible form by mouth or administered parenterally during prolonged therapy with cholestyramine. Reduced serum-folate concentrations have also been reported and it has been suggested that supplementation with folic acid should be considered in such circumstance.
During pregnancy and lactation, RESINCOLESTIRAMINA is not recommended because it can produce a reduction of proper fat-soluble vitamins absorption.

SYMPTOMS AND TREATMENT FOR OVERDOSAGE, AND ANTIDOTE(S)
Overdosage with cholestyramine has been reported in a patient taking 150% of the maximum recommended daily dosage for a period of several weeks. No ill effects were reported. Should and overdosage occur, the chief potential harm would be obstruction of the gastrointestinal tract. The location of such potential obstruction, the degree of obstruction, and the presence or absence of normal gut motility would determine treatment.

PACKING/PACK SIZES
RESINCOLESTIRAMINA is presented in cardboard boxes of 50 sachets of 4 g each one.

STORAGE
To be stored at room temperature (below 30ºC or 86º F).
Shelf-life 5 years.

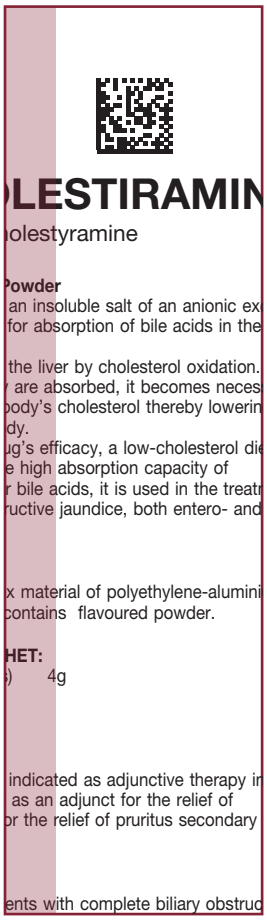
LABORATORIOS RUBIÓ, S.A.
Industria, 29 – Pol. Ind. Comte de Sert
08755 Castellbisbal (Barcelona)
Spain

Medicines should be kept out of the reach of children
PRESCRIPTION ONLY

110P581E

36126100 - 01 20

Conforme:	Producto: **Prospecto Resincolestiramina Singapur**	**CÓDIGOS**
	Material: **Offset 50 g**	Lab. Rubió SA: **36126100**
Fecha:	Tintas: **1+1** Color: **Negro**	Edición: **0120**
	Tamaño: **155 x 240 mm** Hendido y Plegado: **120 x 34 mm** Página: **1**	DataMatrix: (02)00000361261003(99)0120
		G. Maculart: **110P581E**
Edición: 14.01.21	Tipografia: Helvetica Neue LT Pro 57 Cond. Roman, 57 Cond Italic, 77 Bold Condensed	



)LESTIRAMIN

holestyramine

Powder

an insoluble salt of an anionic ex

for absorption of bile acids in the

the liver by cholesterol oxidation.

are absorbed, it becomes neces

body's cholesterol thereby loweri

dy.

ug's efficacy, a low-cholesterol di

e high absorption capacity of

r bile acids, it is used in the treat

ructive jaundice, both entero- and

x material of polyethylene-alumini

contains flavoured powder.

HET:

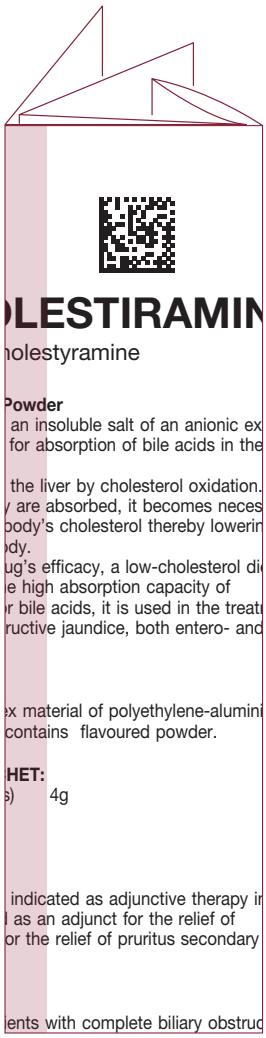
) 4g

indicated as adjunctive therapy i

as an adjunct for the relief of

or the relief of pruritus secondary

ents with complete biliary obstruc



)LESTIRAMIN

holestyramine

Powder

an insoluble salt of an anionic ex

for absorption of bile acids in the

the liver by cholesterol oxidation.

are absorbed, it becomes neces

body's cholesterol thereby loweri

dy.

ug's efficacy, a low-cholesterol di

e high absorption capacity of

r bile acids, it is used in the treat

ructive jaundice, both entero- and

x material of polyethylene-alumini

contains flavoured powder.

HET:

) 4g

indicated as adjunctive therapy i

as an adjunct for the relief of

or the relief of pruritus secondary

ents with complete biliary obstruc