

Life feels good.

Founded
1968

Location
Castellbisbal, Barcelona, Spain

Main Focus
CNS, Nephrology, Urology, Cardiovascular, Gastroenterology, Rheumatology/Orthopedic, Oncology/Radiotherapy, Gynecology.

About Rubió
For more than 55 years Rubió, a family-owned company, has been recognized for the development, manufacture and marketing of medicines with high therapeutic value for specialists as well as of certain drugs for life-threatening diseases, with long expertise in niche markets.

Rubió's determination to meet the health needs of every single patient has led the company to be distinguished as per being pioneer of products targeted to low incidence diseases which affect only a small number of patients and that require the development of specific pharmaceutical products to treat them.

International Alliances and Partnering Strategy
Rubió has established a strong network of partnerships through in and out activities and commercial distribution agreements. Rubió has been in the export business since 1982 and has alliances in over 70 countries. Rubió is constantly exploring new territories and partnerships.

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Cholestyramine

Combination treatment with hypolipidemic agents & first line treatment for cholestatic pruritus and diarrhea caused by bile acid malabsorption^(1,3)



General Information

Brand: Resincolestiramina®
API: Cholestyramine
Presentation: Box containing 50 sachets of 4 g.

Indications²

- Treatment of hypercholesterolaemia: lowering of total and LDL-cholesterol levels in patients with primary hypercholesterolaemia, including familial hypercholesterolaemia, or secondary as a supplement to diet and other treatments, when the response to these measures proves inadequate.
- Pruritus associated to partial biliary obstruction or primary biliary cirrhosis.
- Diarrhea caused by bile acid malabsorption associated with Crohn's disease, intestinal resection, vagotomy, or other conditions that cause excess bile acids in the intestine.

Competitives Advantages

- Resincolestiramina® shows proven efficacy in the reduction of LDL-c either as a monotherapy or in combination with hypolipidemic agents.³
- Good safety profile, non-systemic absorption.
- Low cost in daily treatment.
- Resincolestiramina® is effective in patients with diarrhea caused by bile acid malabsorption and induces a significant reduction in the number of bowel movements.^(2, 4)

Registration and Marketing Authorization

- Dossier available as generic application.
- Marketed in Spain since 1971.
- To be registered as generic of Questran® or the corresponding Reference Product in the country where the application is made. Cholestyramine is not absorbed in the gastrointestinal track. Therefore, BE cannot be demonstrated through bioavailability studies. According to the EU Guideline on equivalence studies for the demonstration of therapeutic equivalence for locally applied, locally acting products in the gastrointestinal tract, the therapeutic equivalence with the originator has been demonstrated with in vitro studies conducted following the recommendations of the FDA Draft Guidance on Cholestyramine. Like the Originator, Resincolestiramina® is available in Orange Flavour.
- Marketed in AE, AR, CA, CL, CU, CY, DK, FI, GT, HN, HK, HU, JO, MT, MX, NI, NL, PA, PL, PT, RS, SA, SE, SG, SI, TH, US and UY.
- Under registration process in KZ, MN, MY, NZ, RU and UZ.
- Marketing Authorization in PE.

Deal Design

- We are looking for partners having a relevant sales structure in Cardiovascular Diseases (Cardiologists) as well as Gastroenterology. Resincolestiramina® is a Business Opportunity either for:
 - a) Partners interested in increasing market share in the treatment of cholesterol, pruritus and diarrhea caused by bile acid malabsorption.
 - Or for
 - b) Partners in countries with high market presence of Cholestyramine may be interested in marketing as the first generic of Questran®
- Deal design consisting of a Supply & Distribution and/or Licensing Agreement to market the Finished Product manufactured by Laboratorios Rubió, S.A.
- We are searching for the best Partners to develop trustful, fruitful and long term business partnerships.

REFERENCES: 1. European Association for the Study of the Liver. EASL Clinical Practice Guidelines: management of cholestatic liver diseases. J Hepatol. 2009 Aug;51(2):237-67. doi: 10.1016/j.jhep.2009.04.009. Epub 2009 Jun 6. PMID: 19501929.

2.FICHA TÉCNICA RESINCOLESTIRAMINA. Disponible en: https://cima.aemps.es/cima/pdfs/es/ft/49340/FichaTecnica_49340.html.pdf

3.Alder M, Bavishi A, Zumpf K, Peterson J, Stone NJ. A meta-analysis assessing additional LDL-C reduction from addition of a bile acid sequestrant to statin therapy. Am J Med. 2020;133(11):P1322-27.

4.Stotzer PO, Abrahamsson H, Bajor A, Sadik R. Effect of cholestyramine on gastrointestinal transit in patients with idiopathic bile acid diarrhea: a prospective, open-label study. Neurogastroenterology. 2013;2: