



# CHOLESTYRAMINE

Combination treatment with hypolipidemic agents & first line treatment for cholestatic pruritus<sup>1</sup> and diarrhea caused by bile acid malabsorption



## General Information

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

## Indications

- 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.
- Puritus 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.
- Excellent 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.

## 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 tract. 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with the originator has been demonstrated with in vitro studies conducted following the recommendations of the FDA Draft Guidance on Cholestyramine.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, CA, CL, CU, CY, DK, FI, GT, HN, HU, JO, MT, MX, NI, NL, PA, PE, PT, RS, SA, SE, SG, SI, TH and US.
- Under registration process in VN.
- MA available in AR.

## 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:
  - Partners interested in increasing market share in the treatment of cholesterol and pruritus, Or for
  - 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 Rubiό, S.A.
- We are searching for the best Partners to develop trustful, fruitful and long term business partnerships.

REFERENCES: 1. Mach F, Baigent C, Catapano AL, Koskinas KC, Casula M, Badimon L, et al. 2019 ESC/EAS Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk. Eur Heart J. 2020 Jan 1;41(1):111-188.

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Millington GWM, Collins A, Lovell CR, Leslie TA, Yong ASW, Morgan JD, et al. British Association of Dermatologists' guidelines for the investigation and management of generalized pruritus in adults without an underlying dermatosis, 2018. Br J Dermatol. 2018;178(1):34-60

 **Rubiό** 55

We are **pharmacypathfinders**

## Founded

1968

## Location

Castellbisbal, Barcelona, Spain

## Main Focus

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

## About Rubiό

For 55 years Laboratorios Rubiό, 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.

Laboratorios Rubiό'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

Laboratorios Rubiό has established a strong network of partnerships through in and out activities and commercial distribution agreements. Laboratorios Rubiό has been in the export business since 1982 and has alliances in over 60 countries. Laboratorios Rubiό is constantly exploring new territories and partnerships.

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