

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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Methylphenidate Hydrochloride MR

The first line treatment for
Attention Deficit Hyperactivity Disorder (ADHD)



General Information

Brand:	Rubifen LA®/ Rubifen Prolong®
API:	Methylphenidate Hydrochloride
Formulation:	Modified Release
Main Presentation:	Boxes containing 30 capsules of 10/20/30/40/60 mg in Blisters Other presentations can also be available.

Indications

- Treatment for children (over 6 years old), adolescents and adults with Attention Deficit Hyperactivity Disorder (ADHD).

Characteristics

- Rubifen LA® is a bioequivalent generic of Ritalin LA® (reference drug) in the treatment of ADHD with:
  - 50% immediate release and 50% modified release
  - Initial recommended dose: 20mg
  - Clinical efficacy not affected by the meals [1 2]
  - Capsule can be opened and the content can be mixed with food
  - Nearly 20 years of clinical experience guaranteed by Ritalin LA as a safe product
- Therapeutic effect within eight-ten hours after intake [3 4]
- Lactose, gluten, egg and latex free

Registration and Marketing Authorization

- Methylphenidate Hydrochloride Modified Release as generic of Ritalin® LA with own Trademark Rubifen LA® or generic name Methylphenidate LA.
- e-CTD Dossier with BE. Registration in new countries as Generic of Ritalin® LA, preferable as First Generic.
- Marketed in AR, AU, BO, DE, DK, EE, ES, IL, NZ, PL, PT, SE, UK, UY & ZA
- Under registration process in HK, IT & UA.

Deal Design

- We are looking for Distributors and/or Licensing Partners having a relevant sales structure in Central Nervous System (CNS) diseases to do a proper promotion of Rubifen LA®/Prolong® brand name or with a long sales expertise in the Generic Business to market it as a generic of Ritalin® LA.
- Deal design consisting on a Supply & Distribution and/or Licensing & Supply Agreement to market the Finished Product manufactured by Laboratorios Rubió,S.A.in agreed countries.
- We are searching for the best Partners to develop trustful, fruitful and long term business partnerships.

REFERENCES: 1.Haessler F, Tracik F, Dietrich H, Stammer H, Klatt J. A pharmacokinetic study of two modified-release methylphenidate formulations under different food conditions in healthy volunteers. Int J Clin Pharmacol Ther. 2008; 46(9):466-76. - 2. Schulz E, Fleischhaker C, Hennighausen K, Heiser P, Haessler P, Linder M et al. A randomized, rater-blinded, crossover study comparing the clinical efficacy of Ritalin® LA (methylphenidate) treatment in children with attention-deficit hyperactivity disorder under different breakfast conditions over 2 weeks. ADHD Atten Def Hyp Disord. 2010; 2:133–38. - 3.Maldonado R. Comparison of the pharmacokinetics and clinical efficacy of new extended-release formulations of methylphenidate. Expert Opin Drug Metab Toxicol. 2013; 9(8): 1001-14. - 4. The American Psychiatric Publishing Textbook of Psychiatry, Sixth Edition.