

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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Lisdexamfetamine Dimesylate

Long-acting psychostimulant prodrug for the treatment of Attention Deficit Hyperactivity Disorder (ADHD)



General Information

Name: Lisdexamfetamine Rubió
API: Lisdexamfetamine dimesylate
Main Presentations: 20/30/40/50/60/70 mg of 30 capsules

Indications

Lisdexamfetamine Rubió is a treatment for Attention Deficit Hyperactivity Disorder (ADHD). It is used:

- In children, young people and adults who have previously taken a methylphenidate treatment that inadequately treated their ADHD.
- Lisdexamfetamine Rubió is not used as a treatment for ADHD in children under 6 years of age because it is not known if it is safe or of benefit in such young people.

Characteristics

Lisdexamfetamine Rubió contains the active substance lisdexamfetamine dimesylate which helps with the brain activity. It helps improve the attention, helps to concentrate and makes the patient less impulsive.

Lisdexamfetamine Rubió is a long acting medicine which works gradually over a 13 hour time period.

Lisdexamfetamine Rubió improves the activity of certain parts of the brain which are under-active. The medicine can help improve attention, concentration and reduce impulsive behaviour ^{1,2,3}

Registration and Marketing Authorization

- CTD dossier will be available with Bioequivalence (BE) with Elvanse®/ Vyvanse® in Q3 2026.
- Registration in new countries as Generic of Elvanse®, preferable as First Generic.

Deal Design

- We are looking for Distributors and/or Licensing Partners having a relevant sales structure in CNS to do a proper promotion of the products or with a long sales expertise in the Generic Business to market it as a generic of Elvanse®.
- 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. Soutullo C, Banaschewski T, Lecendreux M, Johnson M, Zuddas A, Anderson C, et al. A post hoc comparison of the effects of lisdexamfetamine dimesylate and osmotic-release oral system methylphenidate on symptoms of attention-deficit hyperactivity disorder in children and adolescents. *CNS Drugs* 2013; 27: 743-751. 2. Coghill DR, Joseph A, Sikirica V, Kosinski M, Bliss C, Huss M. Correlations Between Clinical Trial Outcomes Based on Symptoms, Functional Impairments, and Quality of Life in Children and Adolescents With ADHD. *J Atten Disord*. 2017 Aug 24;23(13):1578-1591. 3. Coghill, D.R., Werner-Kiechle, T., Farahbakhshian, S. et al. Functional impairment outcomes in clinical trials of different ADHD medications: post hoc responder analyses and baseline subgroup analyses. *Eur Child Adolesc Psychiatry* 30, 809–821 (2021).