

# GUANFACINE



Rubió 55

We are pharmacypathfinders

## Treatment of Attention Deficit Hyperactivity Disorder (ADHD)



### General Information

Name: Guanfacine Rubió®  
API: Guanfacine Hydrochloride  
Presentation: 1/2/3/4 mg 28 prolonged-released tablets

### Indications

- Guanfacine Rubió is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents 6-17 years old for whom stimulants are not suitable, not tolerated or have been shown to be ineffective.
- Guanfacine Rubió must be used as a part of a comprehensive ADHD treatment programme, typically including psychological, educational and social measures.

### Dose

- For all patients, the recommended starting dose is 1 mg of guanfacine, taken orally once a day. The dose may be adjusted in increments of not more than 1 mg per week. Dose should be individualized according to the patient's response and tolerability.
- Depending on the patient's response and tolerability for Guanfacine Rubió the recommended maintenance dose range is 0.05-0.12 mg/kg/day.
- Dose adjustments (increase or decrease) to a maximum tolerated dose within the recommended optimal weight-adjusted dose range based upon clinical judgement of response and tolerability may occur at any weekly interval after the initial dose.

### Method of Administration

- Oral use.
- Guanfacine is taken once daily either morning or evening. Tablets should not be crushed, chewed or broken before swallowing because this increases the rate of guanfacine release.
- Treatment is recommended only for children who are able to swallow the tablet whole without problems.
- Guanfacine can be administered with or without food but should not be administered with high fat meals, due to increased exposure.
- Guanfacine should not be administered together with grapefruit juice.

### Registration and Marketing Authorization

- CTD dossier will be available with Bioequivalence (BE) with Intuniv® in Q2 2025.
- Registration in new countries as Generic of Intuniv®, 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 Intuniv®.
- 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.

### Founded

1968

### Location

Castellbisbal, Barcelona, Spain

### Main Focus

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

### About Rubió

For 55 years Laboratorios 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.

Laboratorios 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 Partnership Strategy

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

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