



# MELATONIN 2 mg

**Improving sleep quality in adults with insomnia**



## General Information

Name: Melatonin Rubiò 2mg prolonged-release tablets  
API: Melatonin  
Main presentations: 21 or 30 tablets

## Indications

▪ Monotherapy for the short-term treatment of primary insomnia characterized by poor quality of sleep in patients who are aged 55 or over.

## Characteristics

▪ Dose: 2 mg once daily, 1-2 hours before bedtime and after food. This dosage may be continued for up to thirteen weeks.

▪ Modified-release melatonin causes the blood concentration over time to more closely mimic a naturally occurring melatonin profile.

## Registration and Marketing Authorization

▪ CTD dossier available with Bioequivalence (BE) with Circadin®.  
▪ Registration in new countries as Generic of Circadin®, preferable as First Generic.  
▪ Marketing Authorizations in AU, DK, FR, IS, IT & NZ.

## Deal Design

▪ We are looking for Distributors and/or Licensing Partners having a relevant sales structure in Primary Care & Psychiatry to do a proper promotion of Melatonin 2mg or with a long sales expertise in the Generic Business to market it as a generic of Circadin®.  
▪ Deal design consisting of a Supply & Distribution and/or Licensing Agreement to market the Finished Product manufactured by Laboratorios Rubiò, S.A.  
▪ We are searching for the best Partners to develop trustful, fruitful and long term business partnerships.



**Rubiò 55**

**We are pharmacypathfinders**

## Founded

1968

## Location

Castellbisbal, Barcelona, Spain

## Main Focus

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

## About Rubiò

For 55 years Laboratorios Rubiò, 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 Rubiò'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 Rubiò has established a strong network of partnerships through in and out activities and commercial distribution agreements. Laboratorios Rubiò has been in the export business since 1982 and has alliances in over 60 countries. Laboratorios Rubiò is constantly exploring new territories and partnerships.

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