rubió

SPECIALITY PHARMACEUTICALS PORTFOLIO

EXPERIENCE
QUALITY
INNOVATION

SINCE 1968



OUR HISTORY

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 being a pioneer of products targeted to low-incidence diseases which affect only a small number of patients and require the development of specific pharmaceutical products to treat them.

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.

1968
FOUNDED

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OUR SPECIALTY PHARMACEUTICALS PORTFOLIO

Rubió develops, manufactures and markets high value specialty pharmaceutical products focused on areas where medical needs require specific and innovative treatment solutions.

Our portfolio is composed of branded and value-added medicines with a solid scientific foundation, used by specialists in key therapeutic areas.

DEAL DESIGN

We are looking for Distributors and/or Licensing Partners having a relevant sales structure in our therapeutic areas to do a proper promotion of our products, or with a long sales expertise in the Generic Business.

Deal design consisting on a Supply & Distribution and/or Licensing & Supply Agreement to market the Finished Products 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.

18
SPECIALITY PHARMACEUTICAL PRODUCTS

70+
COUNTRIES WHERE WE ARE PRESENT

55+
YEARS OF EXPERIENCE

QUALITY
EUROPEAN QUALITY STANDARDS THROGHOUT OUR VALUE CHAIN

MAIN FOCUS

- CNS
- Nephrology
- Urology
- Cardiovascular
- Gastroenterology
- Rheumatology

SPECIALTY PHARMACEUTICALS


CNS 05


Nephrology 17


Urology / Andrology 20


Cardiovascular 22


Gastroenterology 24

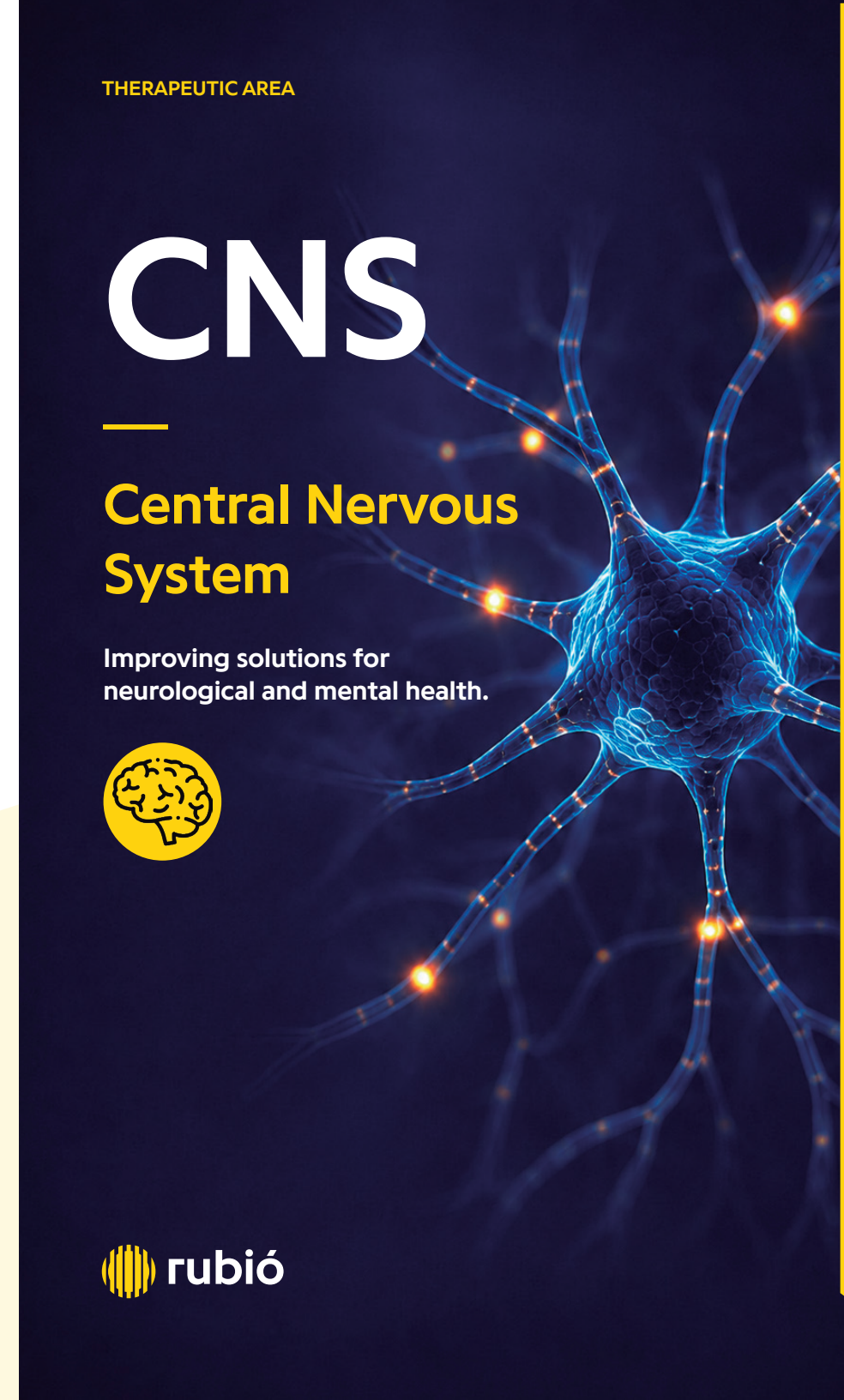

Rheumatology 26

THERAPEUTIC AREA

CNS

Central Nervous System

Improving solutions for neurological and mental health.



rubió

CNS

CENTRAL NERVOUS SYSTEM

Methylphenidate Hydrochloride IR

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

GENERAL INFORMATION

Brand: Rubifen®
API: Methylphenidate Hydrochloride
Formulation: Immediate Release (IR)
Main presentations: Box containing 30 tablets of 5/10/20 mg. Other presentations are also available.

INDICATIONS

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

CHARACTERISTICS

- IR enables very flexible dosage adjustments for picky eater patients, slow growth patients and to avoid insomnia.
- Economical treatment option.
- Over 25 years of clinical experience guarantee Rubifen® as a safe product.
- Therapeutic effect within the first hour after intake with a duration of 4 hours.
- Initial Dosage: 5mg one or two times per day.
- Lactose, gluten, egg and latex free.

REGISTRATION AND MARKETING AUTHORIZATION

- First Methylphenidate Hydrochloride launched in Spain (1983) with own Trademark Rubifen®.
- New e-CTD Dossier in Q4 2027.
- Registration in new countries as Generic of Ritalin® (IR), preferable as First Generic.
- Rubifen® is the top international-sale product of Rubió, marketed already in several countries such as AD, AR, CL, DE, NL, DK, GT, IL, IQ, LK, NI, DO, PA, PT, NZ, MT, MX, TH, UK, UY, ZA.
- In registration process in MM & VN.

CNS

CENTRAL NERVOUS SYSTEM

Methylphenidate Modified Release

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

GENERAL INFORMATION

Brand:	Rubifen LA®/ Rubifen Prolong®
API:	Methylphenidate Hydrochloride.
Formulation:	Modified Release (MR)
Main presentations:	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.

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.

CNS

CENTRAL NERVOUS SYSTEM

Methylphenidate Modified Release

OROS-type prolonged-release methylphenidate for the treatment of ADHD

GENERAL INFORMATION

Brand:	Methylphenidate modified release Rubió
API:	Methylphenidate Hydrochloride
Formulation:	Modified Release
Main presentation:	Boxes containing 30 tablets of 18/27/36/54 mg in Blisters

INDICATIONS

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

CHARACTERISTICS

- Methylphenidate modified release Rubió is a bioequivalent generic of Concerta® (reference drug)

in the treatment of ADHD with:

- 22% immediate release and 78% modified release
- Osmotic modified release system
- Initial recommended dose: 18mg
- Clinical efficacy not affected by the meals
- Capsule can be opened and the content can be mixed with food
- Nearly 20 years of clinical experience guaranteed by Concerta® as a safe product
- Therapeutic effect within twelve hours after intake
- Lactose, gluten, egg and latex free

REGISTRATION AND MARKETING AUTHORIZATION

- Methylphenidate Hydrochloride Modified Release as generic of Concerta®.
- e-CTD Dossier in Q1 2029.

Lisdexamfetamine Dimesylate

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

GENERAL INFORMATION

Brand:	Lisdexamfetamine Rubió
API:	Lisdexamfetamine dimesylate
Main presentations:	20/30/40/50/60/70 mg of 30 hard 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 Q1 2027.
- Registration in new countries as Generic of Elvanse®, preferable as First Generic.

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. C oghill, 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).

CNS

CENTRAL NERVOUS SYSTEM

Guanfacine

Treatment of Attention Deficit Hyperactivity Disorder (ADHD)

GENERAL INFORMATION

Brand: Guanfacine Rubió®
API Guanfacine Hydrochloride
Main presentations: 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 Q1 2028.
- Registration in new countries as Generic of Intuniv®, preferable as First Generic.

CNS

CENTRAL NERVOUS SYSTEM

Atomoxetine

Non-stimulant treatment for Attention Deficit Hyperactivity Disorder (ADHD)

GENERAL INFORMATION

Brand: Atomoxetine Rubió

API: Atomoxetine

Packs: 10/18/25/40/60/80/100mg in 28 hard capsules

INDICATIONS

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

Disorder (ADHD).

CHARACTERISTICS

- Clinical efficacy not affected by the meals .
- Provides continuous 24-hour symptom control, with therapeutic effects beginning within 2–4 weeks of treatment.
- Lactose, gluten, egg and latex free.

REGISTRATION AND MARKETING AUTHORIZATION

- CTD dossier available next Q2 2028 with BE with Strattera®

CNS

CENTRAL NERVOUS SYSTEM

Melatonin 1 mg/ml Oral Solution

Helping to sleep the young ADHD patients

GENERAL INFORMATION

Brand: Conciliax®

API: Melatonin.

Main presentations: 1mg/ml oral solution 60/100/150 ml ambar plastic bottle with 5ml syringe for a better dosing for kids.

INDICATIONS

- Sleep onset insomnia in children and adolescents (6-17 years of age) with attention deficit hyperactivity disorder (ADHD) where other healthy sleeping routines have not worked well enough.
- Short-term treatment of jet lag in adults.

COMPETITIVE ADVANTATGES

- Plastic bottle.
- Syringe doser for kids.
- Child proof cap.
- Strawberry flavour.
- Contains Sorbitol.

REGISTRATION AND MARKETING AUTHORIZATION

- Bibliographic dossier available for 60, 100 and 150ml formats to be submitted according to Article 10a of Directive 2001/83/EC (well-established medicinal use).
- Spain as first launching market in Q1 2027 for 60 ml.

Melatonin 2mg

Improving sleep quality in adults with insomnia

GENERAL INFORMATION

Brand: Melatonin Rubió
API: Melatonin.
Main presentations: 2mg 30 or 90 prolonged-release 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.
- Marketed in AU, BE, DK, ES, FR, IS, IT, LU, PT, NZ & UK.
  Marketing Authorization in ZA.
  Under registration process in AE, IL & TW.

CNS

CENTRAL NERVOUS SYSTEM

Brivaracetam

Modified Release Film-Coated Tablets

GENERAL INFORMATION

Brand: Brivaracetam Rubió

API: Brivaracetam

Main presentations: 50/100/150/200mg 30 modified release film-coated tablets.

INDICATIONS

- Epilepsy.
- It is used in adults, adolescents and children from 2 years of age.
- It is used to treat a type of epilepsy that has partial seizures with or without a secondary generalization. Partial seizures are fits that start by only affecting one side of the brain. These partial seizures can spread and extend to larger areas on both sides of the brain – this is called a 'secondary generalization'.

  This medicine lowers the number of fits (seizures) the patient has.
- It is used together with other medicines for epilepsy.

COMPETITIVE ADVANTATGES

Instead of using 2 tablets per day with the modified release presentation with one tablet is enough.

REGISTRATION AND MARKETING AUTHORIZATION

- CTD with BE with Briviact® for Q1 2029.

Brivaracetam

10 mg/ml Oral Solution

GENERAL INFORMATION

Brand: Brivaracetam Rubió

API: Brivaracetam

Main presentations: 10 mg/ml Oral Solution 300 ml glass bottle with 5ml & 10ml syringes for a better dosing.

INDICATIONS

- Epilepsy.
- It is used in adults, adolescents and children from 2 years of age.
- It is used to treat a type of epilepsy that has partial seizures with or without a secondary generalization. Partial seizures are fits that start by only affecting one side of the brain. These partial seizures can spread and extend to larger areas on both sides of the brain – this is called a 'secondary generalization'.

  This medicine lowers the number of fits (seizures) the patient has.
- It is used together with other medicines for epilepsy.

REGISTRATION AND MARKETING AUTHORIZATION

- CTD for Q1 2029.

CNS

CENTRAL NERVOUS SYSTEM

Nucleodol Pro® Food suplement

DAILY DOSE (2 capsules)		
Alpha-lipoic acid	200 mg	
Acetyl-L-carnitine	200 mg	
PEA (Palmitoylethanolamide)	150 mg	
Cytidine 5'-monophosphate disodium salt (CMP)	100 mg	
Uridine 5'-monophosphate disodium salt (UMP)	100 mg	
Coenzyme Q10	4 mg	
Linseed oil powder	66,8 mg	
Vitamine B6	2,8 mg	200% NRV*
Vitamine B1	2,2 mg	200% NRV*
Folic Acid	400 µg	200% NRV*
Vitamine B12	5 µg	200% NRV*
Zinc	3 mg	30% NRV*

*Nutrient Reference Value (NRV)

CATEGORY

Food supplement

KEY INGREDIENTS

Ultra-micronized Palmitoylethanolamide (PEA), Alpha Lipoic Acid, CMP and UMP

WARNINGS

Do not exceed the stated recommended daily dose. Keep out of the reach of young children. Food supplements should not be used as a substitute for a varied and balanced diet and a healthy lifestyle. It is advisable to consult your doctor before using this product. In rare cases, lipoic acid may cause hypoglycaemia.

INGREDIENT-BASED FORMULATION:

The unique formula of Nucleodol Pro includes palmitoylethanolamide (PEA), a substance naturally produced by the body to help soothe discomfort and restore homeostasis. It also contains nucleotides (CMP & UMP), components involved in important cellular processes. Alpha-lipoic acid and Zinc contribute to the protection of cells against oxidative stress, while B-group vitamins (B1, B6 and B12) contribute to the normal functioning of the nervous system, normal psychological function and energy metabolism.

THERAPEUTIC AREA

NEPHROLOGY

Solutions for Kidneys health and electrolytes balance

Commited to advancing renal care



rubió

RENAL

NEPHROLOGY

Sodium Polystyrene Sulfonate

Effective and safe treatment in the management of Hyperkalaemia

GENERAL INFORMATION

Brand: Resinsodio®

API: Sodium Polystyrene Sulphonate

Presentation: 400 g multi-dose plastic bottle with a measuring spoon that holds approx. 5 g of powder

Pharmaceutical form: Powder for oral/rectal suspension

INDICATIONS

- Treatment and prevention of hyperkalaemia in adults and children.

COMPETITIVE ADVANTATGES

- Resinsodio® has showed efficacy in the reduction of potassium.
- Sugar free.
- Non-systemic absorption.
- Low cost in daily treatment.
- For patients with hypercalcemia.

CLINICAL STUDIES

- Clinical bibliographical data available for the active ingredient.

REGISTRATION AND MARKETING AUTHORIZATION

- Bibliographical dossier available (well -established medicinal use).
- Resinsodio® marketed in Spain since 1968. To be registered as well established medicinal use. The originator is Kayexalate® / Resonium-A®. Sodium polystyrene sulphonate is an insoluble, locally acting, with no systemic absorption substance. The bioequivalence study is not a suitable way to show therapeutic equivalence for this type of products. Bridging to data on formulations described in literature should be justified based on qualitative and quantitative composition. In some particular cases, an "in vitro" study of Resinsodio® against the originator or the reference product in the country is required.
- Marketed in CL, CU, CY, FR, ML, NL, SG, TH, TT & UY.
- Under registration process in HK & GR.

Calcium Polystyrene Sulfonate

Effective and safe treatment option in the management of Hyperkalaemia

GENERAL INFORMATION

Brand: Resincalcio®
API: Calcium Polystyrene Sulphonate
Presentations: 15 g x 26 sachets
400 g multi-dose plastic bottle with a measuring spoon that holds approx. 5 g.
Pharmaceutical form: Powder for oral/rectal suspension

INDICATIONS

- Treatment and prevention of hyperkalaemia in adults and children.

COMPETITIVE ADVANTATGES

- Resincalcio® has showed efficacy in the reduction of potassium.
- Resincalcio® is indicated for patients treated with dialysis with hyperkalaemia.
- Sugar free.
- Non-systemic absorption.
- Low cost in daily treatment.

CLINICAL STUDIES

- Clinical bibliographical data available for the active substance.

REGISTRATION AND MARKETING AUTHORIZATION

- Bibliographical dossier available (well-established medical use).
- Resincalcio® is marketed in Spain since 1968.
- To be registered as well established medicinal use drug:The originator is Calcium Resonium® / Kayexalate Calcium®. Calcium polystyrene sulphonate is an insoluble, locally acting, with no systemic absorption substance. The bioequivalence study is not a suitable way to show therapeutic equivalence for this type of products. Bridging to data on formulations described in literature should be justified based on qualitative and quantitative composition. In some particular cases, an “in vitro” study of Resincalcio® against the originator or the reference product in the country is required.
- Marketed in CL, CU, DE, DO, GT, HN, HR, KW, LU, MX, MY, NI, PH, SA, SG, TH, UK and VN.

THERAPEUTIC AREA

UROLOGY / ANDROLOGY

Advancing male health through innovative solutions

Commited to improving men's health and quality of life.



rubió

Tadalafil ODT

Erectile dysfunction and benign prostatic hyperplasia treatments

GENERAL INFORMATION

Brand: Tadalafil ODT Rubió
API: Tadalafil
Main presentations: 5/10/20 mg Orally Disintegrating Tablets (ODT)
Packs of 2, 4, 6, 8, 12, 14, 28 and 84 tablets.

INDICATIONS

- Treatment of erectile dysfunction in adult males.
- In order for tadalafil to be effective for the treatment of erectile dysfunction, sexual stimulation is required.
- 5 mg only: Treatment of the signs and symptoms of benign prostatic hyperplasia in adult males.
- The product is not indicated for use by women.

COMPETITIVE ADVANTATGES

- The tablet is disintegrated in just few seconds and no water required.
- The product can be used anywhere and anytime: discreete & practical.

REGISTRATION AND MARKETING AUTHORIZATION

- The CTD file will be available in Q2 2027.
- BE with Cialis®.

Testosterone Injectable

When testosterone declines, restoring balance matters.

GENERAL INFORMATION

Brand: Testosterone Rubió
API: Testosterone undecanoate
Main Presentation: 1000 mg/4 mL amber glass vial

INDICATIONS

It is used for the testosterone replacement therapy in male hypogonadism, when testosterone deficiency has been confirmed by clinical findings and biochemical tests.

CHARACTERISTICS

It is the generic of Reandron/Nebido®.

REGISTRATION AND MARKETING AUTHORIZATION

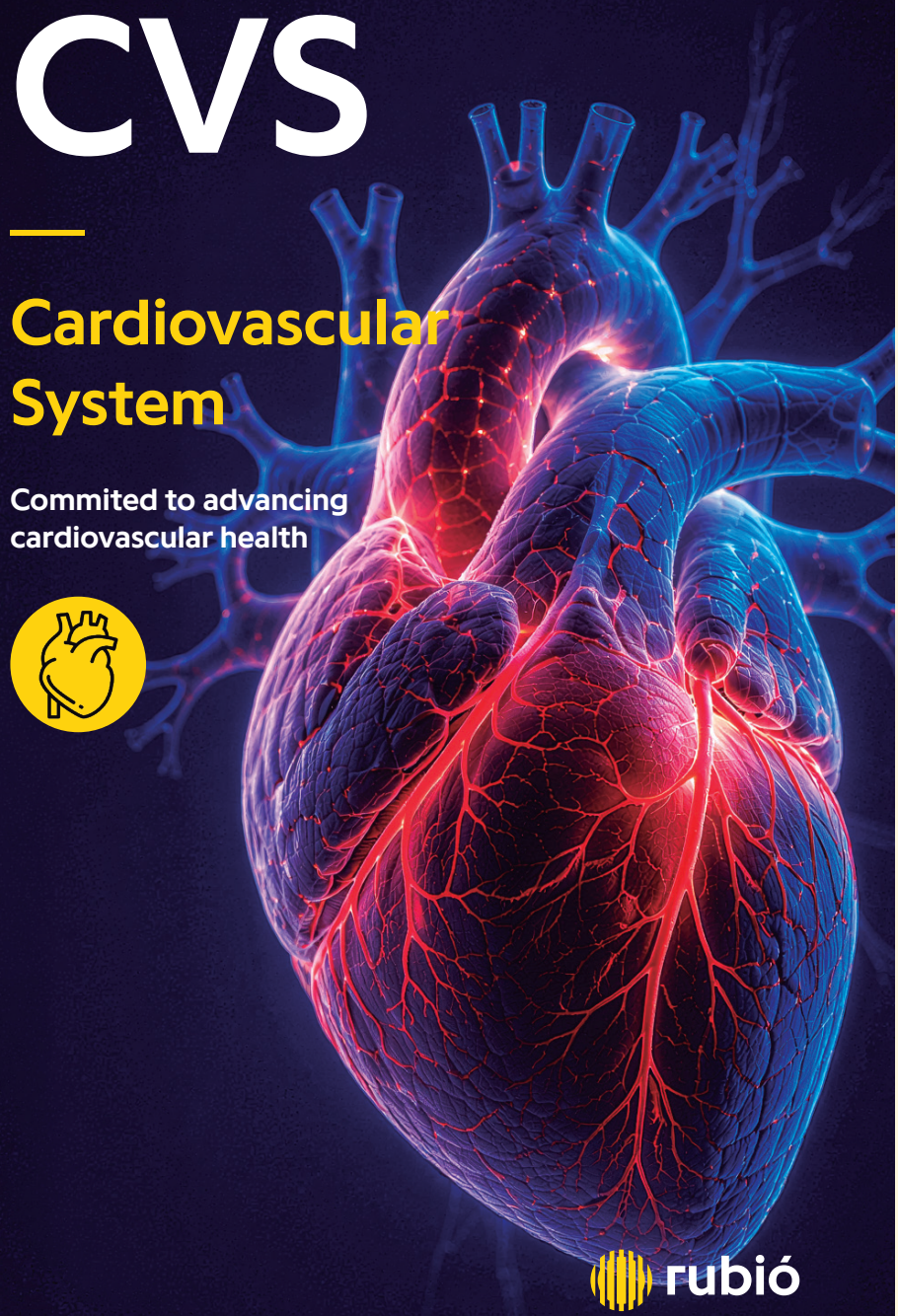
- CTD dossier available next Q1 2028.

THERAPEUTIC AREA

CVS

Cardiovascular System

Commited to advancing cardiovascular health



rubió

Hydralazine Hydrochloride

GENERAL INFORMATION

Brand:	Hydrapres® Injectable
API:	Hydralazine hydrochloride
Main presentations:	20mg 5 ampoules with powder for injection

INDICATIONS

- Severe essential hypertension, when the oral route is not possible or a reduction in blood pressure is required urgently. Pre-eclampsia and eclampsia.

ACTIVITY[1]

- Peripheral vasodilator with a direct mechanism of action that acts primarily on the arteries, causing direct relaxation of arteriolar smooth muscle. Hydralazine is a direct-acting vasodilator of the systemic arterioles. In addition, it alters calcium metabolism by interfering with calcium movement.

REGISTRATION AND MARKETING AUTHORIZATION

- Registered and marketed in Spain from 1984.
- CTD blibliographical dossier available.
- Registered and marketed in CU, DO, GT, HN, NI, PA and UY.
- Registration process in IQ.

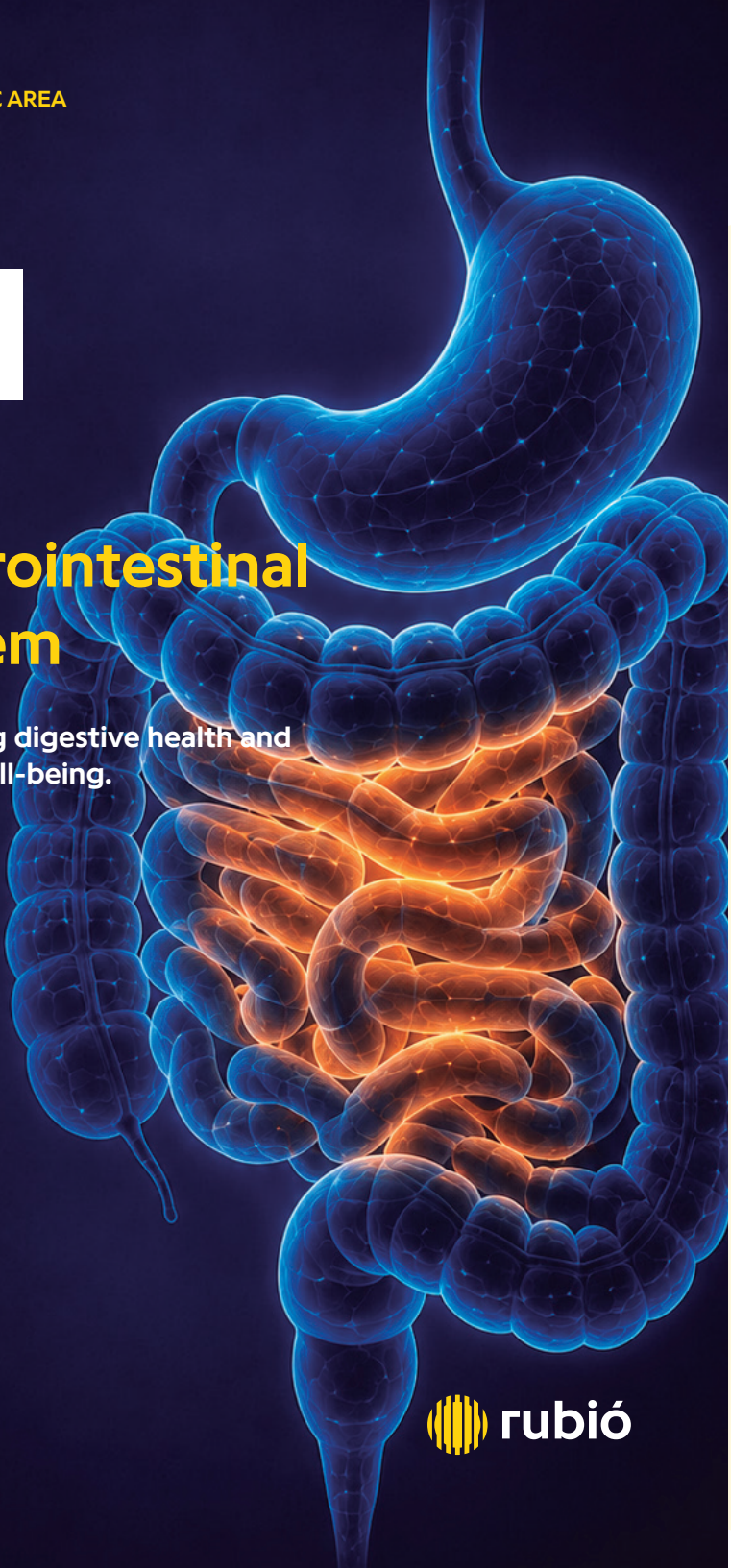
(1) Knowles HJ, Tian YM, Mole DR, Harris AL. Novel mechanism of action for hydralazine: induction of hypoxia-inducible factor-1α, vascular endothelial growth factor, and angiogenesis by inhibition of prolyl hydroxylases. Circ Res. 2004;95(2):162-9.

THERAPEUTIC AREA

GI

Gastrointestinal System

Supporting digestive health and patient well-being.



rubió

GASTROINTESTINAL SYSTEM

Cholestyramine

Combination treatment with hypolipidemic agents & first line treatment for cholestatic pruritus and diarrhea caused by bile acid malabsorption[1,3]

GENERAL INFORMATION

Brand: Resincolestiramina®
API: Cholestyramine
Main presentations: 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.
- Pruritus 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.

COMPETITIVE ADVANTAGES

- Resincolestiramina® shows proven efficacy in the reduction of LDL-c either as a monotherapy or in combination with hypolipidemic agents.[3]
- Good 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.[2, 4]

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 track. 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, AR, CA, CL, CU, CY, DK, FI, GT, HN, HK, HU, JO, MT, MX, NI, NL, PA, PL, PT, RS, SA, SE, SG, SI, TH, US and UY.
- Under registration process in KZ,MN, MY, NZ, RU and UZ.
- Marketing Authorization in PE.

REFERENCES: 1. European Association for the Study of the Liver. EASL Clinical Practice Guidelines: management of cholestatic liver diseases. J Hepatol. 2009 Aug;51(2):237-67. doi: 10.1016/j.jhep.2009.04.009. Epub 2009 Jun 6. PMID: 19501929.

2.FICHA TÉCNICA RESINCOLESTIRAMINA. Disponible en: https://cima.aemps.es/cima/pdfs/es/ft/49340/FichaTecnica_49340.html.pdf

3.Alder M, Bavishi A, Zumpf K, Peterson J, Stone NJ. A meta-analysis assessing additional LDL-C reduction from addition of a bile acid sequestrant to statin therapy. Am J Med. 2020;133(11):P1322-27.

4.Stotzer PO, Abrahamsson H, Bajor A, Sadik R. Effect of cholestyramine on gastrointestinal transit in patients with idiopathic bile acid diarrhea: a prospective, open-label study. Neurogastroenterology. 2013;2:

THERAPEUTIC AREA

Rheumatology

Lupus - RA

Commited to improving patient's quality of life.



rubió

Rheumatology

Lupus - RA

Hydroxychloroquine

Effective and safe treatment option in the management of Lupus & Rheumatoid arthritis

GENERAL INFORMATION

Brand: Hydroxychloroquine Rubió®
API: Hydroxychloroquine Sulfate
Main presentations: 200 mg x 30 film-coated tablets packaged in Blisters.

INDICATIONS

- Rheumatoid Arthritis (joints inflammation)
- Treatment of non-acute and non-complicate Malaria attacks and prevention of Malaria
- Systemic and discoid Lupus Erythematosus (skin or internal organs illness)

COMPETITIVE ADVANTAGES

- Coated tablets which allows better patient swallowing.
- Rubió is the leader in Spain with 95% of market share with this molecule.

REGISTRATION AND MARKETING AUTHORIZATION

- Rubió has marketed this molecule in Spain since 2002
- To be registered as Generic of the originator (Plaquenil®, Sanofi's Reference Product). Bio-equivalence (BE) study with Plaquenil® will be available in the CTD file ready in Q4 2026.
- Rubió markets this molecule in DO, ES, IQ, LB & RS.



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October 2026