

REGURIN® XL (trospium chloride) once daily capsules now available in the UK for the treatment of overactive bladder

7 September 2009, London: Regurin® XL (trospium chloride), a once-daily, prolonged-release capsule to treat patients with overactive bladder (OAB) has been launched in the UK. Regurin® XL provides rapid, significant and consistent improvements in the symptoms of OAB¹ and has a reduced potential for central nervous system (CNS) side effects²⁻⁷.

OAB, also known as irritable bladder, is a condition that results from sudden, involuntary contraction of the muscle in the wall of the urinary bladder. Key symptoms of OAB include frequent urination, urgency of urination, and urge incontinence. Urinary incontinence is a distressing and often embarrassing problem estimated to affect over a third of women in the UK over 40⁸.

By rapidly, significantly and consistently improving the symptoms of OAB as early as day 5 of treatment, a statistically significantly higher number of patients in placebo controlled clinical trials achieved a reduction in urgency and wet days by week 12 with Regurin® XL¹. Furthermore, Regurin® XL has the benefit of not crossing the blood-brain barrier, or the blood eye barrier^{2,4,7}, reducing the CNS side effects sometimes associated with OAB treatments²⁻⁷.

“Overactive bladder has a significant, and often underestimated, impact on the quality of life of all patients. In elderly dependent patients OAB can cause breakdown in care-giving relationships and even increase the likelihood of patients being admitted to a nursing home,” said Professor Linda Cardozo, Kings College Hospital, London. “It is important to effectively treat OAB, to maintain confidence and independence in all patients. Ensuring patient compliance is an important consideration in treating patients with OAB. Therefore, the availability of cost effective, tried and tested treatment, with the convenience of once-daily dosing, and minimal side effects is welcome news for physicians and their patients.”

Clinical trials showed the incidence of dry mouth, and constipation also occurs less frequently in patients on Regurin® XL compared to all other antimuscarinic agents, and approximately 50% less than Regurin® 20mg twice daily^{9,10}. In addition, Regurin® XL has a low potential for interaction with concomitantly administered medications¹¹⁻¹³. Geoff McMillan, Chief Executive Officer of SEP, said: “As a young Company with a focus on Urology, the launch of Regurin XL is very exciting. Urinary incontinence is a very common and embarrassing problem and we believe that Regurin XL offers significant benefits for patients, their physicians and the health service as a whole.”

Regurin® XL is licensed for use in men and women to treat the symptoms of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with OAB.

Exclusive distribution rights in the UK for Regurin® XL (trospium chloride), have been granted to Speciality European Pharma Ltd (SEP), a UK based, urology focused, speciality pharmaceutical company by RottapharmIMadaus.

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About Regurin® XL

Regurin is trospium chloride, a member of the anti-muscarinic class, used to treat the symptoms of OAB. The efficacy has been well established. Trospium chloride has been recommended by NICE for the second line treatment of UI in women after immediate release oxybutynin¹⁴. Regurin XL has a high selectivity for two receptors in the detrusor muscle, M sub(2) and M sub(3)¹⁵.

Regurin® XL is a quaternary amine: as such it is a positively charged molecule that does not cross the blood brain barrier or the blood eye barrier^{2,4,7} hence unwanted side effects such as impairment of cognitive function are minimal²⁻⁷ - an important consideration especially for the elderly population.

About Speciality European Pharma

Founded in April 2006, SEP is a privately owned speciality pharmaceutical company. Its mission is to become the leading urologist focused speciality pharmaceutical business in Europe.

SEP owns worldwide rights to Plenaxis®. Plenaxis is a novel product – it is the first in a new class of hormonal products (the GnRH blockers) and it is used to treat advanced and metastatic prostate cancer. Plenaxis has been launched in Germany and is going through the regulatory process in other EU countries.

SEP has distribution rights in certain European countries for two further products, Amphocil®, an antifungal agent and Haemopressin®, a product for the treatment of Bleeding Oesophageal Varices. Both of these products are delivered to clinicians in a hospital setting.

SEP has established its own commercial operations in the UK, Germany, France and Italy and will market its products in other regions and territories through relationships with expert partners.

About Rottapharm|Madaus

Established in 1961, Rottapharm is a multinational pharmaceutical company primarily engaged in the research, development and global distribution of new pharmaceutical products in different therapeutic areas including rheumatology, cardiology, gastroenterology, gynaecology paediatrics, dermatology, urology, oncology, bronchopneumology, psychiatry.

The headquarters and main R&D site are located in Italy.

Rottapharm has recently acquired the global German pharmaceutical Group Madaus Pharma and today the Rottapharm|Madaus Group has subsidiaries or direct commercial operations throughout Europe and in the vast majority of countries in Middle East, Asia (excluding Japan) and Central/South America.

Currently, Rottapharm's main products include: the original glucosamine sulfate EU prescription product that paved the way for several nutraceutical glucosamines with yet unsurpassed clinical expertise in the development of disease modifying drugs in osteoarthritis; a line of matrix transdermal delivery systems for HRT and CVD; and others out of a list of 19 new drugs derived from over 300 patents. Moreover, the Group has recently implemented a line of effective and successful nutraceuticals for dyslipidemias, women's health, inflammation, and entered the area of personal care that includes a line of leading products in intimate hygiene/paediatric/skin care and in which the company is ranked as the sixth largest in the world market.

Finally, with the acquisition of Madaus, Rottapharm's expertise in the genito-urinary area has been strongly improved. Important synergies have been identified in this area, where the Rottapharm/Madaus Group is benefiting not only the ongoing clinical research activities but also the presence on the market of leading products such as Spasmo Urgenin (relief of painful urinary symptoms) and Spasmolyt/Uraplex/Regurin (overactive bladder), and Uralyt (urolithiasis).

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