



**EUSA**Pharma

**NOVEL RAPYDAN® GAINS MARKETING AUTHORISATION IN EU  
FOR THE RELIEF OF PAIN ASSOCIATED WITH NEEDLE PUNCTURE AND CANNULATION**

**25 February 2008 Oxford, UK** – EUSA Pharma today announced that Rapydan® (70 mg lidocaine/70 mg tetracaine medicated plaster) has now received marketing authorisation in Sweden, the UK, Germany, the Netherlands, France, Spain, Austria, the Czech Republic, Greece, Ireland, Norway and Portugal following the completion of the European Mutual Recognition Procedure. Rapydan® is the first anaesthetic plaster to be approved in over a decade that works faster than the current standard of care and provides high levels of efficacy in pain relief to children and adults requiring needle punctures and cannulations.<sup>1,2</sup>

Rapydan® obtained regulatory marketing authorisation in Sweden in January 2007. EUSA began launching Rapydan® in other European Union countries starting early in 2008.

“Since the launch of Rapydan® in Sweden in 2007, the plaster has been broadly received among the healthcare community,” said Stefan Lundeberg, MD, Pain Treatment Service, Department of Paediatric Anaesthesia and Intensive Care at Astrid Lindgren Children's Hospital, Karolinska University Hospital. “The use of Rapydan® has already widely impacted the relief of pain associated with needle punctures and cannulations, especially among children, throughout Sweden, and is a long-awaited addition to our pain relief armoury in the field of topical anaesthesia.”

The easy-to-use plaster works by combining two local anaesthetic agents (lidocaine and tetracaine) with a breakthrough CHADD® (controlled heat-assisted drug delivery) system and was licensed from ZARS Pharma, Inc. The novel CHADD system combined with the choice of the two local anaesthetic agents enables Rapydan®'s fast onset of action.

Venepuncture and IV insertions are the two most common sources of pain in hospitalised children. In fact, IV insertions and blood draws were the most frequently reported painful events.<sup>3</sup>

Rapydan® is indicated for surface anaesthesia of normal intact skin in connection with needle puncture in adults and children from 3 years of age. It is also indicated for cases of superficial surgical procedures on normal intact skin in adults.

“We are delighted that Rapydan® is now approved to provide pain relief for patients requiring needle punctures and cannulations,” said Bryan Morton, Chief Executive Officer of EUSA Pharma. “Rapydan® is an important product for our company and represents a major opportunity in key markets, and we look forward to a series of successful launches throughout Europe.”

**-ENDS-**

## **Editor’s Notes**

### **About European Mutual Recognition Procedure approval**

The Mutual Recognition Procedure (MRP) is one of the three marketing authorisation procedures in Europe. The procedure is based on the mutual recognition by Concerned Member States of a national marketing authorisation granted by a first Reference Member State. At the end of the Mutual Recognition Procedure, a national marketing authorisation will be issued in each of the Concerned Member States. Harmonisation of the marketing authorisations obtained via a MRP is maintained through subsequent procedures for variations, line extensions and renewals.<sup>4</sup>

Sweden was the Reference Member State and 18 countries\* were Concerned Member States for the Rapydan MRP.

\* Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Luxembourg, Netherlands, Norway, Poland, Portugal, Spain, United Kingdom

### **About EUSA Pharma**

EUSA Pharma is a rapidly growing transatlantic specialty pharmaceutical company focused on inlicensing, developing and marketing late-stage oncology, pain control and critical care products. The company currently has six products on the market, including the antibiotic surgical implant Collatamp® G, Erwinase® and Kidrolase® for the treatment of acute lymphoblastic leukemia, and Rapydan®, a rapid-onset anaesthetic plaster. EUSA also has several products in late-stage development, notably Collatamp® G topical, a gentamicin impregnated collagen sponge for the prevention and treatment of infected skin ulcers, and CollaRx® bupivacaine implant for local post-surgical pain control.

For more information please visit [www.eusapharma.com](http://www.eusapharma.com).

### **About Rapydan®**

Rapydan® 70mg / 70 mg medicated plaster. Each plaster contains 70 mg of lidocaine and 70 mg of tetracaine. Indication: for surface anaesthesia of the normal intact skin in connection with needle puncture in adults and children from 3 years of age, and in cases of superficial surgical procedures on normal intact skin in adults. Posology: Adults: 1 or at most 4 plasters simultaneously; maximum 4 plasters per 24 hours. Children from 3 years of age: 1 or at most 2 plasters simultaneously; maximum 2 plasters per 24 hours. Application time: 30 minutes. Please note that Rapydan® contains a heat-releasing component that may reach a temperature of up to 40°C. Contraindications: Hypersensitivity to the active substances, to local anaesthetics of the amide or ester type, to para-aminobenzoic acid, to sodium borate or to any of the other excipients. Rapydan® should not be used on mucous membranes or on areas with a compromised skin barrier. Special warnings and precautions for use: Use with caution in patients with significant hepatic, renal or cardiac impairment, and in subjects with increased sensitivity to systemic circulatory effects of lidocaine and tetracaine. A prolonged application time or application of more plasters than recommended can lead to increased absorption of lidocaine and tetracaine. Rapydan® contains methyl parahydroxybenzoate and propyl parahydroxybenzoate which may cause allergic reactions. Rapydan® should be used with caution in the proximity of the eyes. Lidocaine has bactericidal and antiviral properties; therefore the result of

intradermal injections of live vaccine should be closely monitored. Interaction with other medicinal products: The risk of additional systemic toxicity should be considered when Rapydan® is used in patients receiving other products containing local anaesthetic agents, or class I and class III antiarrhythmic drugs. Pregnancy and lactation: Pregnancy: use the lowest dose and shortest possible treatment period. Lactation: breast-feeding may continue. Undesirable effects: The most commonly reported adverse drug reactions were local erythema, oedema, blanching and rash. These reactions were generally mild and transient, and disappeared after the end of treatment. Allergic or anaphylactoid reactions associated with lidocaine, tetracaine or other ingredients in Rapydan® may occur. Systemic toxicity and adverse reactions following appropriate use of Rapydan® are unlikely. Prescribers should consult the summary of product characteristics in relation to other side effects. In the event of overdose, the symptoms are expected to be similar to those seen after other local anaesthetic treatment, i.e. excitatory CNS symptoms and, in severe cases, CNS and myocardial depression.

Side effects should be reported promptly to EUSA Pharma Medical Affairs at [medinfo@eusapharma.com](mailto:medinfo@eusapharma.com).

Rapydan® is available by prescription only. Please see full prescribing information available on [www.eusapharma.com](http://www.eusapharma.com).

Rapydan® is a registered trademark of EUSAPharma (Europe)Ltd.  
CHADD® is a registered trademark of ZARS Pharma, Inc.

## Contacts

### For further information, please contact:

Katie Silverwood  
Reynolds-MacKenzie  
Tel. +44 (0)20 7031 4359  
Email: [katie@reynoldsmackenzie.com](mailto:katie@reynoldsmackenzie.com)

Dr Tim Corn  
Chief Medical Officer  
EUSA Pharma  
Tel. +44 (0)1 1865 784260  
Email: [tim.corn@eusapharma.com](mailto:tim.corn@eusapharma.com)

## References:

---

<sup>1</sup> Sethna N *et al.* A Randomized Controlled Trial to Evaluate S-Caine Patch™ [Rapydan®] for Reducing Pain Associated with Vascular Access in Children. *Anesthesiology* 2005; 102:403-8.

<sup>2</sup> Curry SE and Finkel JC. Use of the Synera™ [Rapydan®] Patch for Local Anesthesia Before Vascular Access Procedures: A Randomized, Double-Blind, Placebo-Controlled Study. *American Academy of Pain Medicine* 2007; 8: 497-502.

<sup>3</sup> Wong DL and Baker CM. Pain in Children: Comparison of Assessment Scales *Pediatric Nursing* 1988;14: 9-17.