



Press Release - Regulated information

## UCB to implement full cold-chain for Neupro®

**Neupro® patches should be stored in the refrigerator. Physicians not to initiate any new patients on Neupro® to prioritise supply for existing patients.**

**Brussels, Belgium – June 4, 2008 at 6:00 pm CEST** — UCB announced today that the company will submit a variation to the EMEA (European Medicines Evaluation Agency) to implement a full cold-chain storage and distribution system for Neupro® (rotigotine transdermal patch) in Europe. In agreement with the EMEA, over the next few months, UCB will be replacing current Neupro® supply with product that has been refrigerated from manufacture.

Based on data generated to date, refrigerated storage of Neupro® patches substantially reduces the development of crystals, which can result from the current manufacturing process. Crystallisation in the patch can lead to a change in visual appearance and can theoretically reduce its clinical efficacy, but it is of no clinical relevance in most instances. To date, UCB has not seen a change in the pattern of clinically relevant adverse events, including lack of efficacy, which could be attributed to crystal formation.

All Neupro® supply should be stored in a refrigerator. There is no need for patients to transport Neupro® patches in special containers and they must not be stored in a freezer compartment.

In agreement with the EMEA, and in order to prioritise supply for existing patients, new patients will not be initiated on Neupro®. The company is committed to working with the EMEA so that, as soon as possible, Neupro® can be available again to all patients across Europe, including new patients with Parkinson's Disease and Restless Legs Syndrome (RLS).

"I want to emphasise that the issue is not one of product contamination or toxicity. Patients should use the patches they have and keep their supply in the refrigerator. Even if they notice crystals on their patch, it is important that patients do not stop taking their existing medication without speaking to their doctor," said Iris Loew-Friedrich, MD, PhD, Chief Medical Officer, UCB. "Over the next few months we will be systematically supplying Neupro® that has been refrigerated from manufacture to pharmacies."

In agreement with the EMEA, UCB chose a fast-track standardized regulatory procedure that allows companies to quickly implement changes to information on the safe use of their product.

Neupro® is indicated for the treatment of the signs and symptoms of early-stage and late-stage idiopathic Parkinson's disease in Europe and early stages of the



disease in the US and is distributed by Schwarz Pharma, a company of UCB Group.

### **About Neupro® in Europe and important safety information**

Neupro® (rotigotine transdermal patch) is currently approved for the treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease as monotherapy and as adjunctive therapy with levodopa for advanced-stage Parkinson's disease.

The Committee for Medicinal Products for Human Use (CHMP) of the EMEA has recently issued a positive opinion recommending that the European Commission grants a marketing authorisation for rotigotine transdermal patch in the symptomatic treatment of patients with moderate-to-severe idiopathic RLS.

Rotigotine has been associated with somnolence and episodes of sudden sleep onset, particularly in patients with Parkinson's disease. Sudden onset of sleep during daily activities, in some cases without awareness of any warning signs, has been reported. Pathologic gambling, increased libido and hypersexuality have been reported in patients treated with dopamine agonists for Parkinson's disease, including rotigotine.

It is recommended to monitor blood pressure, especially at the beginning of treatment, due to the general risk of orthostatic hypotension associated with dopaminergic therapy. Hallucinations have been reported and patients should be warned that hallucinations can occur. Caution is advised when treating patients with severe hepatic impairment which may result in lower rotigotine clearance. Adverse drug reactions reported in more than 10% of patients treated with Neupro® transdermal patch are nausea, dizziness, somnolence and application site reactions. Application site reactions are usually mild or moderate in intensity and it is recommended that the application site should be rotated on a daily basis.

Therapy must not be discontinued abruptly. Abrupt withdrawal of dopamine agonists has been associated with a syndrome resembling neuroleptic malignant syndrome or akinetic crises.

### **Further information**

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### **About UCB**

UCB, Brussels, Belgium ([www.ucb-group.com](http://www.ucb-group.com)) is a global leader in the biopharmaceutical industry dedicated to the research, development and commercialization of innovative pharmaceutical and biotechnology products in the fields of central nervous system disorders, allergy/respiratory diseases, immune and inflammatory disorders and oncology. UCB focuses on securing a leading position in severe disease categories. Employing around 12 000 people in over 40 countries, UCB achieved revenue of 3.6 billion Euro in 2007. UCB S.A. is listed on the Euronext Brussels (Euronext: UCB). Schwarz Pharma is a member of UCB-Group.

### **UCB Forward-Looking Statement**

*This press release contains forward-looking statements based on current plans, estimates and beliefs of management. Such statements are subject to risks and uncertainties that may cause actual results to be materially different from those that may be implied by such forward-looking statements contained in this press release. Important factors that could result in such differences include: changes in general economic, business and competitive conditions, effects of future judicial decisions, changes in regulation, exchange rate fluctuations and hiring and retention of its employees.*