European Medicines Agency
Press office

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PRESS RELEASE
EMEA recommends changes in the storage conditions for Neupro (rotigotine)

The European Medicines Agency (EMEA) has recommended the immediate implementation of changes to the product information for Neupro (rotigotine), from Schwarz Pharma Ltd, stating that it must be stored in a refrigerator (at a temperature of between 2ºC and 8ºC). The new storage conditions are intended to reduce the possible occurrence of crystallisation of the active substance which has been reported in patches of Neupro.

Neupro is a centrally-authorised medicine used for the treatment of Parkinson's disease. Its active substance, rotigotine, is a dopamine agonist. Neupro is the only medicine for Parkinson's disease that is administered as a transdermal patch.

At its May 2008 meeting the CHMP has agreed that a phased replacement of all batches of the medicine in the European Union (EU) should be initiated. To avoid a shortage of Neupro, the replacement will take place over 3 months in a step-wise approach. Currently available batches kept in cold storage will be used for the initial supply. New patches manufactured, stored and distributed under complete cold-chain conditions will then replace the existing stock.

The crystals resemble snowflakes and may cover up to 40% of the patch's surface. Data provided by the company indicate that storing Neupro patches at a temperature of between 2ºC and 8ºC reduces the formation of such crystals. The effect of the crystal formation on the efficacy of Neupro is still unclear and is currently under investigation.

It is important that patients do not stop taking their existing medication, even if they notice snowflake crystal patterns on the surface of the patch, without first speaking to their doctor or pharmacist.

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Notes:

1. Neupro was first authorised in February 2006 and is currently available in Austria, the Czech Republic, Denmark, Finland, Germany, Greece, Ireland, Norway, Poland, Spain, Slovakia, Sweden and the United Kingdom.
2. The CHMP reviewed the marketing authorisation of Neupro on the request of the European Commission under Article 20 of Regulation (EC) No 726/2004. This type of procedure is initiated in cases where there are public health concerns with a centrally authorised medicine.
3. Neupro is currently available as 2 mg/24 h, 4 mg/24 h, 6 mg/24 h and 8 mg/24 h transdermal patches. More information is available at the European Public Assessment Report (EPAR) in http://www.emea.europa.eu/humandocs/Humans/EPAR/neupro/neupro.htm
4. More information is available in a question-and-answer document.
5. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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