UCB (Pharma) Ireland Limited
United Drug House, Magna Drive, Magna Business Park, Citywest Rd, Dublin 24

Important Notification

Neupro® 2mg/24h Transdermal Patch

Neupro® 4mg/24h Transdermal Patch

Neupro® 6mg/24h Transdermal Patch

Neupro® 8mg/24h Transdermal Patch

EU/1/05/331/001 - EU/1/05/331/037

All Batches

11th June, 2008
IE PA 016/02

Dear Patient Group Representative,

Following discussions with the Irish Medicines Board (IMB) and the European Medicines Agency (EMEA) we are writing to inform you of an issue relating to the manufacture of Neupro® (rotigotine transdermal patch) which resulted in a recall of certain affected batches of the product across Europe. Neupro® is indicated for the treatment of the signs and symptoms of early-stage and advanced-stage idiopathic Parkinson's disease.

The manufacture of Neupro® can result in an alternative crystalline structure of the active ingredient (rotigotine), which is visible as a snowflake-like pattern and not released from the patch.

Refrigerated storage of Neupro® patches appears to reduce the development of crystals. We are working to implement a full cold-chain distribution system throughout Europe over the next few months. In the meantime the distribution chain will be supplied with new batches to replace the existing stocks at wholesale and pharmacy level.

To this effect, from the end of July 2008 for an interim period the market will only be supplied with the 2mg/24h and 4mg/24h patches.

UCB (Pharma) Ireland Limited
United Drug House, Magna Drive, Magna Business Park, Citywest Rd, Dublin 24

ATTACHMENT: Information sheet to be included in Neupro cartons

Important information!

The product should not be used after the expiry date on the outer carton.

The expiry date on the pouches is not valid.

The product should be stored in the refrigerator. Do not store in the freezer compartment.

Do not be alarmed if you notice "snow flake" - like crystals on the patch.

It is important that you do not interrupt your treatment.

Contact your pharmacist or doctor if you have questions.

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Important Notification

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Neupro® 4mg/24h Transdermal Patch

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Neupro® 8mg/24h Transdermal Patch

EU/1/05/331/001 - EU/1/05/331/037

All Batches

11th June, 2008

IE WH 016/02

Dear Wholesaler,

Following discussions with the Irish Medicines Board (IMB) and the European Medicines Agency (EMEA) we are writing to inform you of an issue relating to the manufacture of Neupro® (rotigotine transdermal patch) which resulted in the recall of certain affected batches of the product across Europe.

Neupro® is indicated for the treatment of the signs and symptoms of early-stage and advanced-stage idiopathic Parkinson's disease.

The manufacture of Neupro® can result in an alternative crystalline structure of the active ingredient (rotigotine), visible as a snowflake-like pattern and not released from the patch.

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Important Notification

Neupro® 2mg/24h Transdermal Patch

Neupro® 4mg/24h Transdermal Patch

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All Batches

11th June, 2008
IE GP 016/02

Dear Doctor,

Following discussions with the Irish Medicines Board (IMB) and the European Medicines Agency (EMEA) we are writing to inform you of an issue relating to the manufacture of Neupro® (rotigotine transdermal patch) which resulted in the recall of certain affected batches of the product across Europe. Neupro® is indicated for the treatment of the signs and symptoms of early-stage and advanced-stage idiopathic Parkinson's disease.

The manufacture of Neupro® can result in an alternative crystalline structure of the active ingredient (rotigotine), visible as a snowflake-like pattern and not released from the patch.

Although in most instances this snowflake-like pattern has no relevance, there is a theoretical possibility that clinical efficacy may be reduced. To date, we have not seen a change in the pattern of clinically relevant adverse events, including lack of efficacy, which could be attributed to crystal formation. Nevertheless, you should be particularly attentive to any signs suggesting a lack of efficacy in patients using this medicinal product. Refrigerated storage of Neupro® patches appears to reduce the development of crystals. We are working to implement a full cold-chain distribution system throughout Europe over the next few months.

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Important Notification

Neupro® 2mg/24h Transdermal Patch

Neupro® 4mg/24h Transdermal Patch

Neupro® 6mg/24h Transdermal Patch

Neupro® 8mg/24h Transdermal Patch

EU/1/05/331/001 - EU/1/05/331/037

All Batches

11th June, 2008
IE DO 016/02

Dear Doctor,

Following discussions with the Irish Medicines Board (IMB) and the European Medicines Agency (EMEA) we are writing to inform you of an issue relating to the manufacture of Neupro® (rotigotine transdermal patch) which resulted in the recall of certain affected batches of the product across Europe. Neupro® is indicated for the treatment of the signs and symptoms of early-stage and advanced-stage idiopathic Parkinson's disease.

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Caution-In-Use Notification

Neupro® 2mg/24h Transdermal Patch
Neupro® 4mg/24h Transdermal Patch
Neupro® 6mg/24h Transdermal Patch
Neupro® 8mg/24h Transdermal Patch

EU/1/05/331/001 - EU/1/05/331/037

All Batches

11th June, 2008
IE PH 016/02

Dear Pharmacist,

Following discussions with the Irish Medicines Board (IMB) and the European Medicines Agency (EMEA) we are writing to inform you of an issue relating to the manufacture of Neupro® (rotigotine transdermal patch) which resulted in the recall of certain affected batches of the product across Europe.

Neupro® is indicated for the treatment of the signs and symptoms of early-stage and advanced-stage idiopathic Parkinson's disease.

The manufacture of Neupro® can result in an alternative crystalline structure of the active ingredient (rotigotine), visible as a snowflake-like pattern and not released from the patch.

Although in most instances this snowflake-like pattern has no relevance, there is a theoretical possibility that clinical efficacy may be reduced. To date, we have not seen a change in the pattern of clinically relevant adverse events, including lack of efficacy, which could be attributed to crystal formation.

Refrigerated storage of Neupro® patches appears to reduce the development of crystals. We are working to implement a full cold-chain distribution system throughout Europe over the next few months.

In agreement with the IMB and the EMEA, we will systematically supply refrigerated Neupro® to replace remaining products in your stock.

It is anticipated that refrigerated Neupro® stock will be available in Ireland from 23rd June, 2008. We will contact you again at that time to confirm the availability of this stock and to make arrangements for the recall of existing Neupro® stock remaining within your pharmacy.

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