

## **Abbreviated Product Information Neupro® Rotigotine**

**Presentation:** Neupro® is a thin, matrix-type square-shaped transdermal patch. Neupro® 2 mg/24 h patch releases 2 mg of rotigotine over 24 hours; each 10 cm<sup>2</sup> patch contains 4.5 mg of rotigotine. Neupro® 4 mg/24 h patch releases 4 mg of rotigotine over 24 hours; each 20 cm<sup>2</sup> contains 9 mg of rotigotine. Neupro® 6 mg/24 h patch releases 6 mg of rotigotine over 24 hours; each 30 cm<sup>2</sup> patch contains 13.5 mg of rotigotine. Neupro® 8 mg/24 h patch releases 8 mg over 24 hours; each 40 cm<sup>2</sup> patch contains 18 mg of rotigotine.

**Therapeutic Indication:** To treat the signs and symptoms of idiopathic Parkinson's disease, either with or without concomitant levodopa therapy.

**Dosage:** In the early stage of Parkinson's disease to use as monotherapy, treatment is initiated as a single daily dose of 2 mg/24 h, and then increased in weekly increments of 2 mg/24 h, up to a maximum of 8 mg/24 h. In the advanced stage of Parkinson's disease and to use in combination with levodopa, treatment initiation is at 4 mg/24 h, and then increased in weekly increments of 2 mg/24 h, up to a maximum dose of 16 mg/24 h. Neupro® is applied once a day. The patch should be applied at approximately the same time every day. The patch remains on the skin for 24 hours and will then be replaced by a new one at a different application site. If the patient forgets to apply the patch at the usual time of the day or if the patch becomes detached, another patch should be applied for the remainder of the day. Neupro should be discontinued gradually.

**Method of administration:** Neupro® is for transdermal use. The patch should be applied to clean, dry, intact healthy skin on the abdomen, thigh, hip, flank, shoulder or upper arm. Reapplication to the same site within 14 days should be avoided. Neupro® should not be placed on skin that is red, irritated or damaged. The patch should be pressed down firmly with the palm of the hand for about 20 to 30 seconds, so that it sticks well. The patch should not be cut into pieces.

**Contraindications:** Hypersensitivity to rotigotine or to any of the excipients. Remove Neupro® prior to any Magnetic Resonance Imaging or cardioversion.

**Precautions:** Dopamine agonists are known to result in hypotension, and monitoring of blood pressure is recommended. Where somnolence or sudden sleep onset occurs, consider dose reduction or termination of therapy. Impulse control disorders (including pathological gambling, increased libido, hypersexuality, compulsive spending or buying, binge eating & compulsive eating) can occur in patients treated with dopamine agonist including rotigotine. Recommend to taper treatment to avoid dopamine agonist withdrawal syndrome (DAWS). Abnormal thinking and behaviour have been reported. Caution is advised when treating patients with severe hepatic impairment. Eye examinations are recommended if vision abnormalities occur. Application site should be rotated on a daily basis to minimize the risk of skin reactions. In case of generalized skin reactions associated with the use of Neupro®, discontinue treatment. Avoid exposure to direct sunlight until the skin is healed. If treatment

is to be withdrawn, it should be gradually reduced to avoid symptoms of neuroleptic malignant syndrome. The incidence of some dopaminergic reactions, such as hallucinations, dyskinesia, and peripheral oedema generally is higher when given in combination with levodopa. Dystonic reactions have occasionally been reported in patients with Parkinson's disease following initiation or incremental dose increase of rotigotine.

**Interactions:** Neuroleptics (e.g. phenothiazines, butyrophenones, thioxanthenes) or metoclopramide, may diminish the effectiveness of Neupro®, and co-administration should be avoided. Caution should be advised when patients are taking sedating medicinal products or other central nervous system depressants (e.g. benzodiazepines, antipsychotics, antidepressants) or alcohol in combination with rotigotine. Neupro® may potentiate the dopaminergic adverse reaction of levodopa and may cause and/or exacerbate pre-existing dyskinesia, as described with other dopamine agonists.

**Undesirable effects:** Very common side effects include somnolence, dizziness, headache, nausea, vomiting, application & instillation site reactions (incl. erythema, pruritus, irritation, rash, dermatitis, vesicles, pain, eczema, inflammation, swelling, discolouration, papules, exfoliation, urticaria, hypersensitivity). Common side effects include perception disturbances (incl. hallucination, hallucination visual, hallucination auditory, illusion), insomnia, sleep disorder, nightmare, abnormal dreams, impulse-control disorders, (incl. pathological gambling, stereotypy/punding, binge eating/eating disorder, compulsive shopping), disturbances in consciousness NEC (incl. syncope, syncope vasovagal, loss of consciousness), dyskinesia, dizziness postural, lethargy, vertigo, palpitations, orthostatic hypotension, hypertension, hiccups, constipation, dry mouth, dyspepsia, erythema, hyperhidrosis, pruritus, oedema peripheral, asthenic conditions (incl. fatigue, asthenia, malaise), weight decreased, fall.

**Storage conditions:** Do not store above 30°C, store in the original package.

Please refer to the *full prescribing information* before prescribing.

Further information is available from: UCB Pharma (Hong Kong) Limited

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