Part VI: Summary of the risk management plan

Summary of risk management plan for Rotigotine-containing transdermal patches (rotigotine)

This is a summary of the risk management plan (RMP) for Rotigotine-containing transdermal patches. The RMP details important risks of Rotigotine-containing transdermal patches and how these risks can be minimised,and how more information will be obtained about risks of Rotigotine-containing transdermal patches and uncertainties (missing information)
Rotigotine-containing transdermal patches´ summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Rotigotine-containing transdermal patches should be used.
Important new concerns or changes to the current ones will be included in updates of Rotigotine-containing transdermal patches´ RMP.

I. The medicine and what it is used for

Rotigotine-containing transdermal patches (1 mg/24h, 2 mg/24h, 3 mg/24h) are authorised for symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome (RLS) in adults.
Rotigotine-containing transdermal patches (2 mg/24h, 4 mg/24h, 6 mg/24h, 8 mg/24h) are authorized as treatment of the signs and symptoms of early-stage idiopathic Parkinson's disease as monotherapy (i.e. without levodopa) or in combination with levodopa, i.e. over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or 'on-off' fluctuations).
It contains rotigotine as the active substance and it is administered as transdermal patch.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Rotigotine-containing transdermal patches, together with measures to minimise such risks and the proposed studies for learning more about Rotigotine-containing transdermal patches´ risks, are outlined below.
Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine´s packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine´s legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimize its risks.

Together, these measures constitute *routine risk minimization measures*.

II.A: List of important risks and missing information

Important risks of Rotigotine-containing transdermal patches are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Rotigotine-containing transdermal patches. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers

to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B: Summary of important risks

There are no important risks for Rotigotine-containing transdermal patches.

II.C: Post-authorization development plan

II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorization or specific obligation of Rotigotine-containing transdermal patches.

II.C.2. Other studies in post-authorization development plan

There are no studies required for Rotigotine-containing transdermal patches.