# Part VI: Summary of the risk management plan

# Summary of risk management plan for Kinparlev (rotigotine)

This is a summary of the risk management plan (RMP) for Kinparlev. The RMP details important risks of Kinparlev, how these risks can be minimized, and how more information will be obtained about Kinparlev's risks and uncertainties (missing information).

Kinparlev's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Kinparlev should be used.

Important new concerns or changes to the current ones will be included in updates of Kinparlev's RMP.

## I. The medicine and what it is used for

Kinparlev is indicated for:

Restless Legs Syndrome

Kinparlev 1 mg/24 h, 2 mg/24 h and 3 mg/24 h transdermal patches are indicated for the symptomatic treatment of moderate to severe idiopathic Restless Legs Syndrome (RLS) in adults.

Parkinson’s disease

Kinparlev 2 mg/24 h, 4 mg/24 h, 6/24 h mg and 8/24 h mg transdermal patches are indicated for the 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 given by transdermal patches (see SmPC for the full information).

## II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Kinparlev, together with measures to minimise such risks and the proposed studies for learning more about Kinparlev's risks, are outlined below.

Measures to minimise 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 minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

## II.A List of important risks and missing information

Important risks of Kinparlev are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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. 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

Safety concerns are adequately addressed in the product information.

The safety information in the product information is aligned to the reference medicinal product.

## II.C Post-authorisation development plan

There are no studies required for Kinparlev.