

Summary of risk management plan for OKEDI® (risperidone)

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

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

This summary of the RMP for OKEDI® should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The medicine and what it is used for

OKEDI® is authorised for the treatment of schizophrenia in adults for whom tolerability and effectiveness has been established with oral risperidone (see SmPC for the full indication). It contains risperidone as the active substance and it is given by intramuscular route of administration as powder and solvent for prolonged-release suspension for injection containing 75 and 100 mg of risperidone. OKEDI® has been developed for administration regimen every 28 days, appropriate for immediate disease management and maintenance of schizophrenia symptoms. OKEDI® provides risperidone blood levels in the therapeutic range after injection and maintaining sustained plasma levels for a period of up to 4 weeks without the need for oral risperidone supplementation.

Further information about the evaluation of OKEDI®'s benefits can be found in OKEDI®'s EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage <https://www.ema.europa.eu/en/medicines/human/EPAR/okedi>.

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

Important risks of OKEDI®, together with measures to minimise such risks and the proposed studies for learning more about OKEDI®'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, including PSUR assessment 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 OKEDI® 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 OKEDI®. 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

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

II.C Post-authorisation development plan

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

There are no studies which are conditions of the marketing authorisation or specific obligation of OKEDI®.

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

There are no studies required for OKEDI®.