

# Summary of risk management plan for Omidria (phenylephrine/ketorolac)

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

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

This summary of the RMP for Omidria 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 Omidria's RMP.

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

Omidria is authorised in adults for maintenance of intraoperative mydriasis, prevention of intraoperative miosis and reduction of acute postoperative ocular pain in intraocular lens replacement surgery (see SmPC for the full indication). It contains phenylephrine and ketorolac as the active substances, and it is given by intraocular irrigation to the affected eye during surgery.

Further information about the evaluation of Omidria's benefits can be found in Omidria'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/omidria>

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

Important risks of Omidria, together with measures to minimise such risks and the proposed studies for learning more about Omidria'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 Omidria 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 Omidria. 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);

<b>List of important risks and missing information</b>	
Important identified risks	None
Important potential risks	None
Missing information	None

## ***II.B Summary of important risks***

None.

## ***II.C Post-authorisation development plan***

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

There are no studies that are conditions of the marketing authorisation or specific obligation of Omidria.

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

There are no studies required for Omidria.