Part VI: Summary of the risk management plan

Summary of risk management plan for VOLTARENOPHTABAK (diclofenac sodium)

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

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

I. The medicine and what it is used for

VOLTARENOPHTABAK is authorised for inhibition of miosis during cataract surgeries, prevention of inflammation in cataract and anterior eye segment surgeries, prevention of cystoid macular oedema after cataract surgery, and treatment of ocular pain in photorefractive keratectomy surgery for up to the 24 first post-operative hours. It contains diclofenac sodium as the active substance and it is given by ocular route.

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

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

Measures to minimise the risks identified for VOLTARENOPHTABAK are:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- 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.

If important information that may affect the safe use of VOLTARENOPHTABAK is not yet available, it is listed under "missing information" below.

II.A List of important risks and missing information

Important risks of VOLTARENOPHTABAK 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 VOLTARENOPHTABAK. 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	• Acute ocular infections • Increased ocular bleeding
Missing information	• Use in paediatric population • Use during pregnancy

II.B Summary of important risks

Important potential risk – Acute ocular infection	
Evidence for linking the risk to the medicine	Evidence is based on spontaneous reports of hypopyon and keratitis.
Risk factors and risk groups	Patients with underlying ocular infection. Concomitant use of immunosuppressive treatments. Use of topical NSAIDs at high dose and during an extended period of time may mask ocular infections.
Risk minimisation measures	<u>Routine risk minimisation measures:</u> • SmPC section 4.4 • PL section 2 • Prescription only medicine

Important potential risk – Increased ocular bleeding	
Evidence for linking the risk to the medicine	Current evidence is based on cases of ocular bleeding reported into the scientific literature.
Risk factors and risk groups	Patients in treatment with antiplatelet or anticoagulant medication. Patients with chronic diseases (hypertension, cardiovascular disease, diabetes mellitus). Use of alcohol or tobacco.

Risk minimisation measures	Routine risk minimisation measures: • SmPC section 4.4 • PL section 2 • Prescription only medicine

Missing information – Use in paediatric population	
Risk minimisation measures	Routine risk minimisation measures: • SmPC section 4.2 • PL section 3 • Prescription only medicine

Missing information – Use during pregnancy	
Risk minimisation measures	Routine risk minimisation measures: • SmPC section 4.6 • PL section 2 • Prescription only medicine

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 VOLTARENOPHTABAK.

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

There are no studies required for VOLTARENOPHTABAK.