Part VI: Summary of the risk management plan

Summary of risk management plan for Ketipinor (quetiapine fumarate)

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

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

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

I. The medicine and what it is used for

Ketipinor is authorised for treatment of schizophrenia, bipolar disorder, and add-on treatment of major depressive episodes (see SmPC for the full indication). It contains quetiapine fumarate as the active substance and it is given by mouth.

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

Important risks of Ketipinor, together with measures to minimise such risks and the proposed studies for learning more about Ketipinor'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 the case of Ketipinor, these measures are supplemented with *additional risk minimisation measures* mentioned under relevant important risks, below.

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*.

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

II.A List of important risks and missing information

Important risks of Ketipinor 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 Ketipinor. 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	• Extrapyramidal symptoms (EPS) • Somnolence • Weight gain • Lipid changes (increased cholesterol [including increased LDLs], increased triglycerides, and decreased HDLs) • Hyperglycaemia and diabetes mellitus • Metabolic risk factors
Important potential risks	• Potential for off-label use and misdosing
Missing information	None

II.B Summary of important risks

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

Important identified risk: Extrapyramidal symptoms (EPS)	
Risk minimisation measures	Routine risk minimisation measures: Information in SmPC sections 4.4, 4.5, 4.6, 4.8 and 5.1, and PL sections 2 and 4. Additional risk minimisation measures: Educational material for healthcare professionals

Important identified risk: Somnolence	
Risk minimisation measures	Routine risk minimisation measures: Information in SmPC sections 4.4, 4.5, 4.6, 4.8, 4.9 and 5.1, and PL sections 2, 3 and 4. Additional risk minimisation measures: Educational material for healthcare professionals

Important identified risk: Weight gain	
Risk minimisation measures	Routine risk minimisation measures: Information in SmPC sections 4.4, 4.5, 4.8 and 5.1, and PL sections 2 and 4. Additional risk minimisation measures: Educational material for healthcare professionals

Important identified risk: Lipid changes (increased cholesterol [including increased LDLs], increased triglycerides, and decreased HDLs)	
Risk minimisation measures	Routine risk minimisation measures: Information in SmPC sections 4.4 and 4.8, and PL section 4. Additional risk minimisation measures: Educational material for healthcare professionals

Important identified risk: Hyperglycaemia and diabetes mellitus	
Risk minimisation measures	Routine risk minimisation measures: Information in SmPC sections 4.4 and 4.8, and PL sections 2 and 4. Additional risk minimisation measures: Educational material for healthcare professionals

Important identified risk: Metabolic risk factors	
Risk minimisation measures	Routine risk minimisation measures: Information in SmPC sections 4.4 and 4.8, and PL sections 2 and 4. Additional risk minimisation measures: Educational material for healthcare professionals

Important potential risk: Potential for off-label use and misdosing	
Risk minimisation measures	Routine risk minimisation measures: Information in SmPC sections 4.1 and 4.2, and PL sections 1 and 3. Additional risk minimisation measures: Educational material for healthcare professionals

II.C Post-authorisation development plan

There are no studies required for Ketipinor.