Part VI: Summary of the risk management plan

Summary of risk management plan for [QUETIAPINE] 50mg, 150mg, 200mg, 300mg, 400mg prolonged- release tablets.

This is a summary of the risk management plan (RMP) for [QUETIAPINE] 50mg, 150mg, 200mg, 300mg, 400mg prolonged- release tablets. The RMP details important risks of [QUETIAPINE] 50mg, 150mg, 200mg, 300mg, 400mg prolonged- release tablets, how these risks can be minimised, and how more information will be obtained about [QUETIAPINE] 50mg, 150mg, 200mg, 300mg, 400mg prolonged- release tablets risks and uncertainties (missing information).
[QUETIAPINE] 50mg, 150mg, 200mg, 300mg, 400mg prolonged- release tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how [QUETIAPINE] 50mg, 150mg, 200mg, 300mg, 400mg prolonged- release tablets should be used.

I. The medicine and what it is used for

[Product name] contains a substance called quetiapine. This belongs to a group of medicines called antipsychotics. [Product name] can be used to treat several illnesses, such as:

- Bipolar depression and major depressive episodes in major depressive disorder: where you feel sad. You may find that you feel depressed, feel guilty, lack energy, lose your appetite or can't sleep.
- Mania: where you may feel very excited, elated, agitated, enthusiastic or hyperactive or have poor judgment including being aggressive or disruptive.
- Schizophrenia: where you may hear or feel things that are not there, believe things that are not true or feel unusually suspicious, anxious, confused, guilty, tense or depressed.

When [Product name] is being taken to treat major depressive episodes in major depressive disorder, it will be taken in addition to another medicine being used to treat this illness.

Your doctor may continue to prescribe [Product name] even when you feel better.

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

Important risks of [QUETIAPINE] 50mg, 150mg, 200mg, 300mg, 400mg prolonged- release tablets, together with measures to minimise such risks and the proposed studies for learning more about [QUETIAPINE] 50mg, 150mg, 200mg, 300mg, 400mg prolonged- release tablets 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.

If important information that may affect the safe use of [QUETIAPINE] 50mg, 150mg, 200mg, 300mg, 400mg prolonged- release tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of [QUETIAPINE] 50mg, 150mg, 200mg, 300mg, 400mg prolonged- release tablets 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 [QUETIAPINE] 50mg, 150mg, 200mg, 300mg, 400mg prolonged- release tablets. 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);

Summary of safety concerns	
Important identified risks	• Extrapyramidal symptoms • Somnolence • Weight gain

	• Lipid changes (increased cholesterol (including increased LDLs), increased triglycerides, and decreased HDLs) • Hyperglycemia and diabetes mellitus • Metabolic risk factors
Important potential risks	• Cerebrovascular adverse effects in elderly patients • Cerebrovascular adverse effects in non-elderly patients • Torsades de Pointes • Ischemic heart disease • Abuse and misuse • Potential for off-label use and misdosing • Suicide and Suicidality
Missing information	• Use in pregnant or lactating women • Use in patients on concomitant cardiovascular medications • Use in patients on concomitant valproic acid

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 [QUETIAPINE] 50mg, 150mg, 200mg, 300mg, 400mg prolonged- release tablets.

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

There are no studies required for [QUETIAPINE] 50mg, 150mg, 200mg, 300mg, 400mg prolonged- release tablets.