# Part VI: Summary of the risk management plan

## Summary of risk management plan for Quetiapine Accord 150 mg prolonged release tablets (Quetiapine fumarate)

This is a summary of the risk management plan (RMP) for Quetiapine Accord 150 mg prolonged release tablets. The RMP details important risks of Quetiapine Accord 150 mg prolonged release tablets, how these risks can be minimised, and how more information will be obtained about Quetiapine Accord 150 mg prolonged release tablets' risks and uncertainties (missing information).

Quetiapine Accord 150 mg prolonged release tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Quetiapine Accord 150 mg prolonged release tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Quetiapine Accord 150 mg prolonged release tablets' RMP.

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

Quetiapine prolonged release tablet is indicated for:

- Treatment of Schizophrenia
- Treatment of bipolar disorder :
  - For the treatment of moderate to severe manic episodes in bipolar disorder
  - For the treatment of major depressive episodes in bipolar disorder
  - For the prevention of recurrence of manic or depressed episodes in patients with bipolar disorder who previously responded to quetiapine treatment.
- Add-on treatment of major depressive episodes in patients with Major Depressive Disorder (MDD) who have had sub-optimal response to antidepressant monotherapy. Prior to initiating treatment, clinicians should consider the safety profile of quetiapine prolonged release tablet.

It contains quetiapine fumarate as the active substance and it is given by oral route.

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

Important risks of Quetiapine Accord 150 mg prolonged release tablets together with measures to minimise such risks and the proposed studies for learning more about Quetiapine Accord 150 mg 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 the case of Quetiapine Accord 150 mg prolonged release tablets, 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 during signal management activity, 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 Accord 150 mg 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 Accord 150 mg 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 Accord 150 mg prolonged release tablets. Potential risks are concerns for which an association with the use

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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).

| | |
|---|---|
| Important identified risks | • Extrapyramidal symptoms (EPS)<br>• Somnolence<br>• Weight gain<br>• Lipid changes (Increased cholesterol [including increased LDLs], increased triglycerides, and decreased HDLs)<br>• Hyperglycemia and diabetes mellitus<br>• Metabolic risk factors<br>• Suicide and suicidality |
| Important potential risks | • Cerebrovascular adverse events in the elderly<br>• Cerebrovascular adverse events in non-elderly patients<br>• Torsades de Pointes<br>• Ischemic heart disease<br>• Abuse and misuse<br>• Potential for off-label use and misdosing |
| Missing information | • Use in pregnant or breast feeding women<br>• Use in patients on concomitant cardiovascular medications<br>• Use in patients on concomitant valproic acid |

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## II.B Summary of important risks

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

| **Important Identified Risk: Extrapyramidal symptoms (EPS)** | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br>Sections 4.4, 4.5, 4.6, 4.8 and 5.1 of Quetiapine SmPC and corresponding section of PIL has information on this safety concern.<br>Other routine risk minimisation measures include the prescription only status of the product.<br>Additional risk minimisation measures:<br>Educational material for physicians (prescribers) |

| **Important Identified Risk: Somnolence** | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br>Sections 4.4, 4.5, 4.6, 4.8 and 5.1 of Quetiapine SmPC and corresponding section of PIL has information on this safety concern.<br>Other routine risk minimisation measures include the prescription only status of the product.<br>Additional risk minimisation measures:<br>Educational material for physicians (prescribers) |

| **Important Identified Risk: Weight gain** |
|---|

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|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br>Sections 4.4, 4.5, 4.8 and 5.1 of Quetiapine SmPC and corresponding section of PIL has information on this safety concern.<br>Other routine risk minimisation measures include the prescription only status of the product.<br>Additional risk minimisation measures:<br>Educational material for physicians (prescribers) |

| **Important Identified Risk: Lipid changes (Increased cholesterol [including increased LDLs], increased triglycerides, and decreased HDLs)** | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br>Sections 4.4 and 4.8 of Quetiapine SmPC and corresponding section of PIL has information on this safety concern.<br>Other routine risk minimisation measures include the prescription only status of the product.<br>Additional risk minimisation measures:<br>Educational material for physicians (prescribers) |

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| **Important Identified Risk: Hyperglycemia and diabetes mellitus** | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br>Sections 4.4 and 4.8 of Quetiapine SmPC and corresponding section of PIL has information on this safety concern.<br>Other routine risk minimisation measures include the prescription only status of the product.<br>Additional risk minimisation measures:<br>Educational material for physicians (prescribers) |

| **Important Identified Risk: Metabolic risk factors** | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br>Sections 4.4 and 4.8 of Quetiapine SmPC and corresponding section of PIL has information on this safety concern.<br>Other routine risk minimisation measures include the prescription only status of the product.<br>Additional risk minimisation measures:<br>Educational material for physicians (prescribers) |

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| **Important Potential Risk: Potential for off-label use and misdosing** | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br>Section 4.2 of Quetiapine SmPC and corresponding section of PIL has information on this safety concern.<br>Other routine risk minimisation measures include the prescription only status of the product.<br>Additional risk minimisation measures:<br>Educational material for physicians (prescribers) |

## 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 Accord 150 mg prolonged release tablets.

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

There are no studies required for Quetiapine Accord 150 mg prolonged release tablets.

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