# Part VI: Summary of the risk management plan

## Summary of risk management plan for Quetiapin Pharmathen (Quetiapine)

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

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

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

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

Quetiapin Pharmathen is authorised 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(see SmPC for the full indication).

It contains Quetiapine as the active substance and it is given by oral route of administration.

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

Important risks of Quetiapin Pharmathen, together with measures to minimise such risks and the proposed studies for learning more about Quetiapin Pharmathen'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 Quetiapin Pharmathen, 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 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 Quetiapin Pharmathen is not yet available, it is listed under 'missing information' below.

## *II.A List of important risks and missing information*

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

## *II.B Summary of important risks*

| **Important identified risk: Extrapyramidal symptoms (EPS)** | |
|---|---|
| Risk minimisation measures | Routine risk minimisation measures:<br><br>SmPC sections 4.4, 4.8 and 5.1 |

| | |
|---|---|
| | PL section 4<br><br>Prescription only medicine<br>Additional risk minimisation measures:<br>Educational Material for Health Care Professionals |
| **Important identified risk: Somnolence** | |
| Risk minimisation measures | Routine risk minimisation measures:<br>SmPC section 4.4, 4.8<br>PL section 4<br><br>Prescription only medicine<br>Additional risk minimisation measures:<br>Educational Material for Health Care Professionals |
| **Important identified risk: Weight gain** | |
| Risk minimisation measures | Routine risk minimisation measures:<br>SmPC sections 4.4, 4.8 and 5.1<br>PL sections 2, 4<br><br>Prescription only medicine<br>Additional risk minimisation measures:<br>Educational Material for Health Care Professionals |
| **Important identified risk: Lipid changes (increased cholesterol [including increased LDLs], increased triglycerides, and decreased HDLs)** | |
| Risk minimisation measures | Routine risk minimisation measures:<br>SmPC section 4.4<br>PL section 4<br><br>Prescription only medicine<br>Additional risk minimisation measures:<br>Educational Material for Health Care Professionals |
| **Important identified risk: Hyperglycaemia and diabetes mellitus** | |
| Risk minimisation measures | Routine risk minimisation measures:<br>SmPC sections 4.4, 4.8<br>PL section 4 |

| | |
|---|---|
| | Prescription only medicine<br>Additional risk minimisation measures:<br>Educational Material for Health Care Professionals |
| **Important identified risk: Metabolic risk factors** | |
| Risk minimisation measures | Routine risk minimisation measures:<br>**SmPC section 4.4, 4.8**<br>Prescription only medicine<br>Additional risk minimisation measures:<br>Educational Material for Health Care Professionals |
| **Important potential risk and missing information: Potential for off-label use and misdosing** | |
| Risk minimisation measures | Routine risk minimisation measures:<br>Prescription only medicine<br>Additional risk minimisation measures:<br>Educational Material for Health Care Professionals |

## *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 Quetiapin Pharmathen.

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

There are no studies required for Quetiapin Pharmathen.