

# **Part VI: Summary of the risk management plan**

## **Summary of risk management plan for Quetiapin Medical "Valley"**

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

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

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

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

Quetiapin Medical "Valley" 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.

Quetiapin Medical "Valley" contains quetiapine as the active substance, and it is given orally.

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

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

These measures constitute *routine pharmacovigilance activities*.

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

Important risks of Quetiapin Medical "Valley" 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 Quetiapin Medical "Valley". 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	<ul style="list-style-type: none"> <li>• Extrapyramidal symptoms</li> <li>• Somnolence</li> <li>• Weight gain</li> <li>• Lipid changes (increased cholesterol (including increased LDLs), increased triglycerides, and decreased HDLs)</li> <li>• Hyperglycemia and diabetes mellitus</li> <li>• Metabolic risk factors</li> </ul>
Important potential risks	<ul style="list-style-type: none"> <li>• Potential for off-label use and misdosing</li> </ul>
Missing information	<ul style="list-style-type: none"> <li>• None</li> </ul>

## II.B Summary of important risks

<b>Important identified risk</b> <b>Extrapyramidal symptoms</b>	
Risk factors and risk groups	Not applicable
<b>Risk minimisation measures</b>	<i>Routine risk minimisation measures:</i> SmPC sections 4.4, 4.8 and 5.1 PIL section 4 <i>Other routine risk minimisation measures:</i> Prescription only medicine <i>Additional risk minimization measures:</i> Educational material for HCPs
<b>Important identified risk</b> <b>Somnolence</b>	
Risk factors and risk groups	Not applicable
<b>Risk minimisation measures</b>	<i>Routine risk minimisation measures:</i> SmPC section 4.4 PIL section 4 <i>Other routine risk minimisation measures:</i> Prescription only medicine <i>Additional risk minimization measures:</i> Educational material for HCPs

<b>Important identified risk</b> <b>Weight gain</b>	
Risk factors and risk groups	Not applicable
<i>Risk minimisation measures</i>	<i>Routine risk minimisation measures:</i> SmPC sections 4.4, 4.8 and 5.1 PIL sections 2 and 4 <i>Other routine risk minimisation measures:</i> Prescription only medicine <i>Additional risk minimization measures:</i> Educational material for HCPs
<b>Important identified risk</b> <b>Lipid changes (increased cholesterol (including increased LDLs), increased triglycerides, and decreased HDLs)</b>	
Risk factors and risk groups	Not applicable
<i>Risk minimisation measures</i>	<i>Routine risk minimisation measures:</i> SmPC section 4.4 PIL section 4 <i>Other routine risk minimisation measures:</i> Prescription only medicine <i>Additional risk minimization measures:</i> Educational material for HCPs
<b>Important identified risk</b> <b>Hyperglycemia and diabetes mellitus</b>	
Risk factors and risk groups	Not applicable
<i>Risk minimisation measures</i>	<i>Routine risk minimisation measures:</i> SmPC sections 4.4 and 4.8 PIL section 4 <i>Other routine risk minimisation measures:</i> Prescription only medicine <i>Additional risk minimization measures:</i> Educational material for HCPs
<b>Important identified risk</b> <b>Metabolic risk factors</b>	
Risk factors and risk groups	Not applicable
<i>Risk minimisation measures</i>	<i>Routine risk minimisation measures:</i> SmPC sections 4.4 and 4.8 <i>Other routine risk minimisation measures:</i> Prescription only medicine <i>Additional risk minimization measures:</i> Educational material for HCPs
<b>Important potential risk</b> <b>Potential for off-label use and misdosing</b>	
Risk factors and risk groups	Not applicable
<i>Risk minimisation measures</i>	<i>Routine risk minimisation measures:</i> SmPC sections 4.2 and 4.4 <i>Other routine risk minimisation measures:</i> Prescription only medicine <i>Additional risk minimization measures:</i> Educational material for HCPs

## 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 Medical "Valley".

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

There are no studies required for Quetiapin Medical "Valley".