Summary of risk management plan for Antoreq 50mg, 150mg, 200mg, 300mg, 400mg, 600mg prolonged-release tablets (Quetiapine)

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

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

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

I. The medicine and what it is used for

Antoreq is authorised for the treatment of Schizophrenia, treatment of bipolar disorder and 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 Antoreq together with measures to minimise such risks and the proposed studies for learning more about Antoreq '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 Guide 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 Antoreq, 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*.

II.A List of important risks and missing information

Important risks of Antoreq 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 Antoreq. 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 • 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	• Potential for off-label use and misdosing
Missing information	• None

II.B Summary of important risks

Important identified risk Extrapyramidal symptoms	
Risk minimisation measures	Routine risk minimisation measures: *SmPC sections 4.4, 4.8 and 5.1* *PL section 4* *Prescription only medicine* Additional risk minimisation measures: *Physician Guide*

Important identified risk Somnolence	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4 PL section 4 Prescription only medicine Additional risk minimisation measures: Physician Guide
Important identified risk Weight gain	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4 PL section 4 Prescription only medicine Additional risk minimisation measures: Physician Guide
Important identified risk Lipid changes (increased cholesterol (including increased LDLs), increased triglycerides, and decreased HDLs)	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4 PL section 4 Prescription only medicine Additional risk minimisation measures: Physician Guide
Important identified risk Hyperglycemia and diabetes mellitus	
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.4, 4.8

	PL section 4 Prescription only medicine Additional risk minimisation measures: Physician Guide
Important identified risk Metabolic risk factors	
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.4, 4.8 Prescription only medicine Additional risk minimisation measures: Physician Guide
Important potential risk Potential for off-label use and misdosing	
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.2, 4.4 Prescription only medicine Additional risk minimisation measures: Physician Guide

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 Antoreq.

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

There are no studies required for Antoreq.