Part VI: Summary of the risk management plan

Summary of risk management plan for [ARIPIPRAZOLE] 5mg, 10mg, 15mg & 30mg tablets

This is a summary of the risk management plan (RMP) for [ARIPIPRAZOLE] 5mg, 10mg, 15mg & 30mg tablets, how these risks can be minimised, and how more information will be obtained about [ARIPIPRAZOLE] 5mg, 10mg, 15mg & 30mg tablets risks and uncertainties (missing information).
[ARIPIPRAZOLE] 5mg, 10mg, 15mg & 30mg tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how [ARIPIPRAZOLE] 5mg, 10mg, 15mg & 30mg tablets should be used.

I. The medicine and what it is used for

[ARIPIPRAZOLE] 5mg, 10mg, 15mg & 30mg tablets contains the active substance aripiprazole and belongs to a group of medicines called antipsychotics.
It is used to treat adults and adolescents aged 15 years and older who suffer from a disease characterized by symptoms such as hearing, seeing or sensing things which are not there, suspiciousness, mistaken beliefs, incoherent speech and behaviour and emotional flatness. People with this condition may also feel depressed, guilty, anxious or tense.

Aripiprazole is used to treat adults and adolescents aged 13 years and older who suffer from a condition with symptoms such as feeling "high", having excessive amounts of energy, needing much less sleep than usual, talking very quickly with racing ideas and sometimes severe irritability. In adults it also prevents this condition from returning in patients who have responded to the treatment with Aripiprazole.

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

Important risks of [ARIPIPRAZOLE] 5mg, 10mg, 15mg & 30mg tablets, together with measures to minimise such risks and the proposed studies for learning more about [ARIPIPRAZOLE] 5mg, 10mg, 15mg & 30mg 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 [ARIPIPRAZOLE] 5mg, 10mg, 15mg & 30mg tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of [ARIPIPRAZOLE] 5mg, 10mg, 15mg & 30mg 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 [ARIPIPRAZOLE] 5mg, 10mg, 15mg & 30mg 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	• Neuroleptic Malignant Syndrome • Extrapyramidal symptoms (EPS), including tardive dyskinesia
Important potential risks	• Seizures • Hyperglycaemia/diabetes • Suicide-related events • Orthostatic hypotension • Dyslipidemia
Missing information	• Use in paediatrics • Use in pregnancy and lactation

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 [ARIPIPRAZOLE] 5mg, 10mg, 15mg & 30mg tablets.

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

There are no studies required for [ARIPIPRAZOLE] 5mg, 10mg, 15mg & 30mg tablets