Summary of risk management plan for Aripiprazole Mylan Pharma/ Aripiprazol Generics/ Aripiprazol Anova/ Aripiprazol Mylan/ ADEXYL (Aripiprazole)

This is a summary of the risk management plan (RMP) for Aripiprazole Mylan Pharma/Aripiprazol Generics/Aripiprazol Anova/ Aripiprazol Mylan/ADEXYL. The RMP details important risks of aripiprazole, how these risks can be minimised, and how more information will be obtained about aripiprazole's risks and uncertainties (missing information).

Aripiprazole Mylan Pharma/Aripiprazol Generics/Aripiprazol Anova/Aripiprazol Mylan/ADEXYL summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how it should be used.

I. The medicine and what it is used for

Aripiprazole Mylan Pharma/ Aripiprazol Generics/ Aripiprazol Anova/ Aripiprazol Mylan/ ADEXYL is authorised for:

- the treatment of schizophrenia in adults and in adolescents aged 15 years and older
- the treatment of moderate to severe manic episodes in Bipolar I Disorder and for the prevention of a new manic episode in adults who experienced predominantly manic episodes and whose manic episodes responded to aripiprazole treatment
- the treatment up to 12 weeks of moderate to severe manic episodes in Bipolar I Disorder in adolescents aged 13 years and older.

It contains aripiprazole as the active substance and it is given by oral route of administration, available in 5 mg/10 mg/15 mg/30 mg tablets and 1 mg / ml oral Solution.

With respect to the centralized procedure, EMEA/H/C/003803, further information about the evaluation of Aripiprazole Mylan Pharma's benefits can be found in Aripiprazole Mylan Pharma's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

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

Important risks of Aripiprazole Mylan Pharma/ Aripiprazol Generics/Aripiprazol Anova/Aripiprazol Mylan/ ADEXYL, together with measures to minimise such 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 public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse events 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 Aripiprazole Mylan Pharma/Aripiprazol Generics/ Aripiprazol Anova/Aripiprazol Mylan/ADEXYL is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of aripiprazole are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered to patients. 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. 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/use in special patient populations etc.).

Summary of safety concerns

List of important risks and missing information	
Important identified risks	Extrapyramidal symptoms including tardive dyskinesia
Important potential risks	Orthostatic hypotension
Missing information	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.

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

There are no studies required for aripiprazole.