Summary of Risk Management Plan for Donepezil Jubilant 5 mg, 10 mg film-coated tablets

This is a summary of the risk management plan (RMP) for Donepezil Jubilant 5 mg, 10 mg film-coated tablets and Lizidra 5 mg, 10 mg compresse rivestite con film.

The RMP details important risks of Donepezil Jubilant 5 mg, 10 mg film-coated tablets and Lizidra 5 mg, 10 mg compresse rivestite con film, how these risks can be minimised, and how more information will be obtained about Donepezil risks and uncertainties (missing information).

Donepezil Jubilant 5 mg, 10 mg film-coated tablets and Lizidra 5 mg, 10 mg compresse rivestite con film summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Donepezil Jubilant 5 mg, 10 mg film-coated tablets and Lizidra 5 mg, 10 mg compresse rivestite con film should be used.

Important new safety concerns or changes to the current ones will be included in updates of the Donepezil 5 mg, 10 mg film-coated tablets RMP.

I. The medicine and what it is used for

Donepezil is indicated for the symptomatic treatment of mild to moderately severe Alzheimer's disease.

Donepezil Jubilant 5 mg, 10 mg film-coated tablets and Lizidra 5 mg, 10 mg compresse rivestite con film contains Donepezil 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 Donepezil Jubilant 5 mg, 10 mg film-coated tablets and Lizidra 5 mg, 10 mg compresse rivestite con film, together with measures to minimise such risks for learning more about Donepezil Jubilant 5 mg, 10 mg film-coated tablets and Lizidra 5 mg, 10 mg compresse rivestite con film 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 PI 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, including signal assessment, as applicable so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

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II.A List of important risks and missing information

Important risks of Donepezil Jubilant 5 mg, 10 mg film-coated tablets and Lizidra 5 mg, 10 mg compresse rivestite con film 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 Donepezil Jubilant 5 mg, 10 mg film-coated tablets and Lizidra 5 mg, 10 mg compresse rivestite con film.

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	• None
Important potential risks	• None
Missing information	• None

II.B Summary of important risks

The safety information in the product information is aligned to the reference medicinal product (Aricept 5/10 mg, film-coated tablets of Eisai GmbH/Pfizer GmbH).

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorization

There are no studies which are conditions of the marketing authorisation or specific obligation of Donepezil Jubilant 5 mg, 10 mg film-coated tablets and Lizidra 5 mg, 10 mg compresse rivestite con film.

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

There are no studies required for Donepezil Jubilant 5 mg, 10 mg film-coated tablets and Lizidra 5 mg, 10 mg compresse rivestite con film.