Part VI: Summary of the risk management plan

Summary of risk management plan for Abbonate 20 mg film-coated tablets (tranylcypromine)

This is a summary of the risk management plan (RMP) for Abbonate 20 mg film-coated tablets. The RMP details important risks of Abbonate tablets, how these risks can be minimised, and how more information will be obtained about Abbonate's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

Abbonate is authorised for the treatment of major depressive episodes in patients with serious multiresistant depression disorder where an adequate treatment with two standard antidepressant drugs (including tricyclic antidepressants) and augmentation with, e.g., lithium, did not provide sufficient success. It contains tranylypromine as the active substance and is given by oral route.

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

Important risks of Abbonate, together with measures to minimise such risks and the proposed studies for learning more about Abbonate'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 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 Abbonate, 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, 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 Abbonate 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 Abbonate. 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	Hypertensive crisis
Important potential risks	None
Missing information	None

II.B Summary of important risks

Important identified risk	
Evidence for linking the risk to the medicine	Tyramine is a naturally occurring substance that is present in certain foods. Some foods contain greater amounts of tyramine than others, e.g., foods that have been aged, fermented, pickled, smoked or that are past the "best before" -date. As high tyramine diet may promote hypertensive crisis in patients that are using MAO inhibitors, this is considered as an important identified risk for Abbonate.
Risk factors and risk groups	The risk is limited to patients who do not comply with dietary restrictions.
Risk minimisation measures	<u>Routine risk minimisation measures</u> SmPC sections 4.4, 4.5 and 4.8 PL sections 2 and 4 <u>Additional risk minimisation measures</u> Patient guide, including patient diary Patient alert card

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 Abbonate, solution for injection.

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

There are no studies required for Abbonate, solution for injection.