Part VI: Summary of the risk management plan

Summary of risk management plan for Varenicline 0.5 mg and 1 mg Film-coated Tablets

This is a summary of the risk management plan (RMP) for Varenicline 0.5 mg and 1 mg Film-coated Tablets. This RMP details about important risks of Varenicline 0.5 mg and 1 mg Film-coated Tablets, how these risks can be minimised, and how more information will be obtained about Varenicline 0.5 mg and 1 mg Film-coated Tablets' risks and uncertainties (missing information).

Varenicline 0.5 mg and 1 mg Film-coated Tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Varenicline 0.5 mg and 1 mg Film-coated Tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Varenicline 0.5 mg and 1 mg Film-coated Tablets' RMP.

I. The medicine and what it is used for

Varenicline 0.5 mg and 1 mg Film-coated Tablets are indicated for smoking cessation in adults.

It contains varenicline as active ingredient and it is given by oral route.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Varenicline 0.5 mg and 1 mg Film-coated Tablets, 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 patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimization measures.

If important information that may affect the safe use of Varenicline 0.5 mg and 1 mg Film-coated Tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Varenicline 0.5 mg and 1 mg Film-coated Tablets are risks that need special risk management activities to further investigate or minimize 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 Varenicline 0.5 mg and 1 mg Film-coated 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).

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• None
Missing information	• Use in patients with cardiovascular diseases (CVD) • Use in pregnancy

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorization development plan

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

There are no studies which are conditions of the marketing authorization or specific obligation of Varenicline 0.5 mg and 1 mg Film-coated Tablets.

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

There are no studies required for Varenicline 0.5 mg and 1 mg Film-coated Tablets.