Part VI: Summary of the risk management plan

Summary of risk management plan for Amitriptyline 10 mg, 25 mg and 50 mg film-coated tablets (Amitriptyline):

This is a summary of the risk management plan (RMP) for amitriptyline 10 mg, 25 mg and 50 mg film-coated tablets. The RMP details important risks of amitriptyline 10 mg, 25 mg and 50 mg film-coated tablets, risk minimisation measures needed to minimise these risks and routine pharmacovigilance activities needed to obtain more information about amitriptyline 10 mg, 25 mg and 50 mg film-coated tablets' risks and uncertainties (missing information).

Amitriptyline 10 mg, 25 mg and 50 mg film-coated tablets' proposed Summary of Product Characteristics (SmPC) and its package leaflet gives essential information to healthcare professionals and patients on how Amitriptyline 10 mg, 25 mg and 50 mg film-coated tablets should be used.
This summary of the RMP for amitriptyline 10 mg, 25 mg and 50 mg film-coated tablets should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of amitriptyline 10 mg, 25 mg and 50 mg film-coated tablets' RMP.

I. The medicine and what it is used for

Amitriptyline 10 mg, 25 mg and 50 mg film-coated tablets are authorised:

- In the treatment of major depressive disorder in adults,
- In treatment of neuropathic pain in adults,
- In the prophylactic treatment of chronic tension type headache (CTTH) in adults,
- In the prophylactic treatment of migraine in adults and
- In the treatment of nocturnal enuresis in children aged 6 years and above.

It contains amitriptyline as the active substance, and it is given by oral route.

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

Important risks of amitriptyline 10 mg, 25 mg and 50 mg film-coated tablets, together with measures to minimise such risks are outlined below.
Measures to minimise the risks identified for amitriptyline 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 amitriptyline 10 mg, 25 mg and 50 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 amitriptyline 10 mg, 25 mg and 50 mg film-coated 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 amitriptyline 10 mg, 25 mg and 50 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;

The safety profile has been sufficiently characterized based on the extensive experience with amitriptyline (first authorised in the 1960s, EURD 31 July 1961), and the safety concerns are sufficiently reflected in the product information.

Important Identified Risk	• None
Important Potential Risk	• None
Missing information	• None

II.B Summary of important risks

The safety information for the other important safety concerns 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 which is a specific obligation of amitriptyline 10 mg, 25 mg and 50 mg film-coated tablets.

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

There are no studies required for amitriptyline 10 mg, 25 mg and 50 mg film-coated tablets.