

Part VI: Summary of the risk management plan

Summary of risk management plan for AMITRIPTILINA DOC

This is a summary of the risk management plan (RMP) for amitriptyline hydrochloride. The RMP details important risks of AMITRIPTILINA DOC, how these risks can be minimised, and how more information will be obtained about amitriptyline hydrochloride risks and uncertainties (missing information).

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

I. The medicine and what it is used for

AMITRIPTILINA DOC is authorised for the treatment of endogenous depression and depressive syndromes of different nature.

Amitriptyline is also indicated in the prophylactic treatment of migraine, chronic or recurrent headaches and for the treatment of peripheral neuropathic pain.

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

Important risks of AMITRIPTILINA DOC together with measures to minimise such risks and the proposed studies for learning more about amitriptyline hydrochloride'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.

If important information that may affect the safe use of amitriptyline hydrochloride is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of AMITRIPTILINA DOC 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 hydrochloride. 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	<ul style="list-style-type: none"> - Suicidality - Hyponatraemia - Brugada Syndrome - Serotonin syndrome - QT prolongation and Torsades de Pointes - Disturbances in consciousness (somnolence, sedation, syncope, coma, coma scale abnormal) - Cardiac arrest and cardio-respiratory arrest - Respiratory arrest with amitriptyline overdose - Use in pregnancy and lactation - Death (including death unexpected, sudden death, accidental death) - Overdose - Use in patients with phaeochromocytoma - Porphyrria
Important potential risks	<ul style="list-style-type: none"> - Schizophrenia, psychosis, hallucinations, paranoid delusions - Hostility/aggression and self injurious ideation in children and adolescents - Nystagmus - Haemodynamic instability (including circulatory collapse)
Missing information	<ul style="list-style-type: none"> - Thyroid adenoma - Encephalopathy - SOC "Congenital, familial and genetic disorders" - Paediatric and adolescent use - Lack of therapeutic efficacy - Off label use

II.B Summary of important risks

The safety information in the authorized 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 AMITRIPTILINA DOC.

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

There are no studies required for AMITRIPTILINA DOC.