

Summary of risk management plan for ASCRIPTIN 100 mg + 27 mg + 23 mg tablets (Acetylsalicylic acid/Magnesium hydroxide/Hydrated aluminium oxide)

This is a summary of the risk management plan (RMP) for "ASCRIPTIN 100 mg + 27 mg + 23 mg tablets". The RMP details important risks of "ASCRIPTIN 100 mg + 27 mg + 23 mg tablets", and how more information will be obtained about "ASCRIPTIN 100 mg + 27 mg + 23 mg tablets' risks and uncertainties (missing information).

"ASCRIPTIN 100 mg + 27 mg + 23 mg tablets' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how "ASCRIPTIN 100 mg + 27 mg + 23 mg tablets" should be used.

Important new concerns or changes to the current ones will be included in updates of "ASCRIPTIN 100 mg + 27 mg + 23 mg tablets" tablets RMP.

I. The medicine and what it is used for

"ASCRIPTIN 100 mg + 27 mg + 23 mg tablets" is authorised for

- 1) Prevention of atherothrombotic events,
- 2) Prevention of graft re-occlusion following aortocoronary by-pass surgery or percutaneous transluminal coronary angioplasty,
- 3) Prevention of cardiovascular events,
- 4) Prevention of cardiovascular events in high-risk patients
(see SmPC for the full indication).

It contains Acetylsalicylic acid/Magnesium hydroxide/Hydrated aluminium oxide as the active substances 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 "ASCRIPTIN 100 mg + 27 mg + 23 mg tablets", together with measures to minimise such risks and the proposed studies for learning more about "ASCRIPTIN 100 mg + 27 mg + 23 mg tablets' 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 addition to these measures, information about adverse reactions is collected continuously and regularly analysed, - including PSUR assessment - 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 "ASCRIPTIN 100 mg + 27 mg + 23 mg tablets" 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 "ASCRIPTIN 100 mg + 27 mg + 23 mg 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	None

II.B Summary of important risks

Not applicable as no important safety concerns are listed in Part II.A of this RMP.

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 "ASCRIPTIN 100 mg + 27 mg + 23 mg tablets".

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

There are no studies required for "ASCRIPTIN 100 mg + 27 mg + 23 mg tablets".