

Summary of Risk Management Plan for Citalopram Jubilant 10, 20, 30, 40 mg film-coated tablet

This is a summary of the risk management plan (RMP) for Citalopram Jubilant 10 mg, 20 mg, 30 mg, 40 mg film coated tablets. The RMP details important risks of Citalopram Jubilant 10 mg, 20 mg, 30 mg, 40 mg film coated tablets, how these risks can be minimised, and how more information will be obtained about Citalopram risks and uncertainties (missing information).

Citalopram Jubilant 10 mg, 20 mg, 30 mg, 40 mg film coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Citalopram Jubilant 10 mg, 20 mg, 30 mg, 40 mg film coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Citalopram Jubilant 10 mg, 20 mg, 30 mg, and 40 mg film coated tablets film coated tablet RMP.

I. The medicine and what it is used for

Citalopram are used in treatment of episodes of major depression and in treatment of panic disorder with or without agoraphobia.

It contains citalopram 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 Citalopram Jubilant 10 mg, 20 mg, 30 mg, 40 mg film coated tablets, together with measures to minimise such risks for learning more about Citalopram Jubilant 10 mg, 20 mg, 30 mg, 40 mg film coated 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.

II.A List of important risks and missing information

Important risks of Citalopram Jubilant 10 mg, 20 mg, 30 mg, 40 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 Citalopram Jubilant.

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	• None
Important potential risks	• Bone fractures
Missing information	• Long-term safety in children and adolescents concerning growth, maturation and cognitive and behavioural development

II.B Summary of important risks

The safety information in the product information is aligned to the reference medicinal product (Cipramil of Lundbeck B.V.)

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 Citalopram Jubilant 10 mg, 20 mg, 30 mg, 40 mg film coated tablets.

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

There are no studies required for Citalopram Jubilant 10 mg, 20 mg, 30 mg, 40 mg film coated tablets.