

Summary of risk management plan for ACIDO URSODESOSSICOLICO ABC 250 mg capsule rigide and ACIDO URSODESOSSICOLICO ABC 500 mg capsule rigide (Ursodeoxycholic acid)

This is a summary of the risk management plan (RMP) for ACIDO URSODESOSSICOLICO ABC 250 mg capsule rigide and ACIDO URSODESOSSICOLICO ABC 500 mg capsule rigide. The RMP details important risks of ACIDO URSODESOSSICOLICO ABC 250 mg capsule rigide and ACIDO URSODESOSSICOLICO ABC 500 mg capsule rigide, how these risks can be minimised, and how more information will be obtained about ACIDO URSODESOSSICOLICO ABC 250 mg capsule rigide and ACIDO URSODESOSSICOLICO ABC 500 mg capsule rigide's risks and uncertainties (missing information).

ACIDO URSODESOSSICOLICO ABC 250 mg capsule rigide and ACIDO URSODESOSSICOLICO ABC 500 mg capsule rigide 's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how ACIDO URSODESOSSICOLICO ABC 250 mg capsule rigide and ACIDO URSODESOSSICOLICO ABC 500 mg capsule rigide should be used

I. The medicine and what it is used for

ACIDO URSODESOSSICOLICO ABC 250 mg capsule rigide and ACIDO URSODESOSSICOLICO ABC 500 mg capsule rigide are authorised for:

- Dissolution of cholesterol gallstones in the gall bladder. The gallstones should be x-ray negative and have a diameter less than 15 mm. The gall bladder must be functioning despite the gallstone(s).
- Primary biliary cirrhosis (PBC) stages I – III.

Paediatric population:

Hepatobiliary disorder associated with cystic fibrosis in children aged 6 years to less than 18 years.

It contains Ursodeoxycholic acid as the active substance and it is given by oral use.

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

Important risks of ACIDO URSODESOSSICOLICO ABC 250 mg capsule rigide and ACIDO URSODESOSSICOLICO ABC 500 mg capsule rigide, together with measures to minimise such risks and the proposed studies for learning more about ACIDO URSODESOSSICOLICO ABC 250 mg capsule rigide and ACIDO URSODESOSSICOLICO ABC 500 mg capsule rigide'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 ACIDO URSODESOSSICOLICO ABC 250 mg capsule rigide and ACIDO URSODESOSSICOLICO ABC 500 mg capsule rigide is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of ACIDO URSODESOSSICOLICO ABC 250 mg capsule rigide and ACIDO URSODESOSSICOLICO ABC 500 mg capsule rigide 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 ACIDO URSODESOSSICOLICO ABC 250 mg capsule rigide and ACIDO URSODESOSSICOLICO ABC 500 mg capsule rigide . 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	<ul style="list-style-type: none">• Hepatic decompensation in primary biliary cirrhosis• Diarrhoea• Biliary colic• Hypersensitivity and skin reactions
Important potential risks	<ul style="list-style-type: none">• Teratogenicity
Missing information	<ul style="list-style-type: none">• Off label use in patients with radio-opaque calcified gallstones, occlusion of biliary tract, frequent episodes of biliary colic and impaired contractility of gall bladder• Off label use in patients with acute inflammation of the gall bladder or biliary tract• Safety in breast feeding

II.B Summary of important risks

The safety information 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 specific obligation of ACIDO URSODESOSSICOLICO ABC 250 mg capsule rigide and ACIDO URSODESOSSICOLICO ABC 500 mg capsule rigide.

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

There are no studies required for ACIDO URSODESOSSICOLICO ABC 250 mg capsule rigide and ACIDO URSODESOSSICOLICO ABC 500 mg capsule rigide.