PART VI: Summary of the risk management plan

Summary of risk management plan for Ursosan 250 mg capsule, hard, Ursosan 400 mg or 500 mg film-coated tablets

This is a summary of the risk management plan (RMP) for Ursosan 250 mg capsule, hard, Ursosan 400 mg or 500 mg film-coated tablets. The RMP details important risks of Ursosan 250 mg capsule, hard, Ursosan 400 mg or 500 mg film-coated tablets, how these risks can be minimised, and how more information will be obtained about Ursosan 250 mg capsule, hard, Ursosan 400 mg or 500 mg film-coated tablets risks and uncertainties (missing information).

Ursosan 250 mg capsule, hard, Ursosan 400 mg or 500 mg film-coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Ursosan 250 mg capsule, hard, Ursosan 400 mg or 500 mg film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Ursosan 250 mg capsule, hard, Ursosan 400 mg or 500 mg film-coated tablets's RMP.

I. The medicine and what it is used for

Ursosan 250 mg capsule, hard is authorised for dissolution of cholesterol gallstones of the gall bladder. The gallstones must not produce any shadows on the radiograph and should not be of a greater diameter than 15 mm. The gall bladder, despite the gallstone(s) must be functioning. It is also indicated for treatment of gall reflux gastritis and also for symptomatic treatment of primary biliary cholangitis (PBC), as long as there is no decompensated cirrhosis of the liver. In Paediatric population it is indicated for treatment of hepatobiliary disorders associated with cystic fibrosis in children aged 6 to 18 years (see product SmPC for the full indication). It contains Ursodeoxycholic acid as the active substance and it is given by oral administration.

Ursosan 400 mg film-coated tablets is authorised for dissolution of cholesterol gallstones of the gall bladder. The gallstones must not show as shadows on X-ray images and should not exceed 15 mm in diameter. The gall bladder must be functioning despite the gallstone(s). It is also indicated for symptomatic treatment of primary biliary cholangitis (PBC), provided there is no decompensated hepatic cirrhosis, for the treatment of dyspeptic disorders which are caused by cholesterol gallstones and/or bile flow disorders. These disorders can manifest as pressure in the upper abdomen, pressure pain and occasionally as colic pain as well as intolerance to fatty meal. In Paediatric population it is indicated for treatment of hepatobiliary disorders associated with cystic fibrosis in children aged 6 to 18 years (see product SmPC for the full indication). It contains Ursodeoxycholic acid as the active substance and it is given by oral administration.

Ursosan 500 mg film-coated tablets is authorised for dissolution of cholesterol gallstones of the gall bladder. The gallstones must not show as shadows on X-ray images and should not exceed 15 mm in diameter. The gall bladder must be functioning despite the gallstone(s). For symptomatic treatment of primary biliary cholangitis (PBC), provided there is no decompensated hepatic cirrhosis. In Paediatric population it is indicated for treatment of hepatobiliary disorders associated with cystic fibrosis in children aged 6 to 18 years (see product SmPC for the full indication). It contains Ursodeoxycholic acid as the active substance and it is given by oral administration.

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

Important risks of Ursosan 250 mg capsule, hard, Ursosan 400 mg or 500 mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about Ursosan 250 mg capsule, hard, Ursosan 400 mg or 500 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, such as warnings, precautions, and advice on correct use;
- 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 public (e.g. with or without prescription) can help to minimises 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 Ursosan 250 mg capsule, hard, Ursosan 400 mg or 500 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 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 Ursosan 250 mg capsule, hard, Ursosan 400 mg or 500 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 (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

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 Ursosan 250 mg capsule, hard, Ursosan 400 mg or 500 mg film-coated tablets.

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

There are no studies required for Ursosan 250 mg capsule, hard, Ursosan 400 mg or 500 mg film-coated tablets.