Part VI: Summary of the risk management plan

Summary of risk management plan for

GRINTEROL® 250 mg hard capsules

(ursodeoxycholic acid)

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

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

Important new concerns or changes to the current ones will be included in updates of Grinterol's RMP.

I. The medicine and what it is used for

Grinterol is authorised for dissolution of cholesterol gallstones and primary biliary cholangitis (PBC, also known as primary biliary cirrhosis) in adults and treatment of hepatobiliary disorders as a result of cystic fibrosis in children and adolescents aged 6 to 18 years. It contains ursodeoxycholic acid as the active substance and it is given orally in concentration of 250 mg per hard capsule.

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

Important risks of Grinterol, together with measures to minimise such risks and the proposed studies for learning more about risks of Grinterol, 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 SPC 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 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 Grinterol 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 Grinterol. 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	*None*
Missing information	*None*

II.B *Summary of important risks*

The safety information in the proposed Product Information is aligned to the reference medical 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 Grinterol.

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

There are no studies required for Grinterol.