PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Dopital 50 mg/100 mg/200 mg Hard Capsules (mexiletine hydrochloride)

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

Mexiletine hydrochloride Hard Capsules' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Mexiletine hydrochloride Hard Capsules should be used.

I. THE MEDICINE AND WHAT IT IS USED FOR

Mexiletine hydrochloride Hard Capsules are authorised for the treatment of ventricular arrhythmias which are considered as life-threatening by the physician (see SmPC for the full indication). It contains mexiletine hydrochloride as the active substance and it is given by mouth.

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

Important risks of Mexiletine hydrochloride Hard Capsules, together with measures to minimise such risks and the proposed studies for learning more about Mexiletine hydrochloride Hard Capsules' 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, 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 Mexiletine hydrochloride Hard Capsules 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 Mexiletine hydrochloride Hard Capsules. 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

Not applicable.

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 Dopital 50 mg, 100 mg, 200 mg Hard Capsules.

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

There are no studies required for Dopital 50 mg, 100 mg, 200 mg Hard Capsules.