Part VI: Summary of the risk management plan

Summary of risk management plan for Glyceryl trinitrate Pharmexon

This is a summary of the risk management plan (RMP) for Glyceryl trinitrate Pharmexon. The RMP details important risks of Glyceryl trinitrate Pharmexon, how these risks can be minimised and how more information will be obtained about Glyceryl trinitrate Pharmexon risks and uncertainties (missing information). Glyceryl trinitrate Pharmexon summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Glyceryl trinitrate Pharmexon should be used.

I. The medicine and what it is used for

Glyceryl trinitrate Pharmexon is authorised for treatment of

- Severe and prolonged ischemic chest pain associated with acute myocardial infarction or unstable *angina pectoris*.
- Left ventricular cardiac insufficiency and pulmonary congestion associated with myocardial infarction.
- Hypertensive conditions associated with open heart surgery and other surgical procedures.
- Hypertensive crisis with symptoms of cardiac decompensation.
- In surgical procedures, to achieve a controlled hypotension.

It contains 1 mg/ml glyceryl trinitrate as the active substance, and it is given by intravenous infusion.

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

Important risks of Glyceryl trinitrate Pharmexon, together with measures to minimise such risks and the proposed studies for learning more about Glyceryl trinitrate Pharmexon'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.

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 Glyceryl trinitrate Pharmexon are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered or 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 Glyceryl trinitrate Pharmexon. 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.

Summary of safety concerns	
Important identified risk	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 Glyceryl trinitrate Pharmexon.

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

There are no studies required for Glyceryl trinitrate Pharmexon.