This is a summary of the risk management plan (RMP) for Trientine 200 mg hard capsules. No important risks are identified for Trientine 200 mg hard capsules however, the RMP details how more information will be obtained about Trientine 200 mg hard capsules' risks and uncertainties (missing information).

Trientine 200 mg hard capsules' summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Trientine 200 mg hard capsules should be used.

Important new concerns or changes to the current ones will be included in updates of Trientine 200 mg hard capsules' RMP.

I. The medicine and what it is used for

Trientine 200 mg hard capsules are authorised for the for the treatment of Wilson's disease in patients intolerant to D-Penicillamine therapy, in adults, adolescents and children aged 5 years or older. It contains trientine dihydrochloride as the active substance and it is given orally by swallowing the hard capsule.

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

Although no important risks have been identified for Trientine 200 mg hard capsules measures to minimise risks and the proposed studies for learning more about Trientine 200 mg 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.

If important information that may affect the safe use of Trientine 200 mg hard capsules is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Trientine 200 mg 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 Trientine 200 mg 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	Drug exposure during pregnancy Use of drug in lactation and in neonates

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

Not applicable

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

There are no studies required for Trientine 200 mg hard capsules.