SUMMARY OF RISK MANAGEMENT PLAN FOR CYCLOSERINE- VERSION 1.0

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

Cycloserine's Summary of Product Characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Cycloserine should be used.

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

I. The medicine and what it is used for

Cycloserine Capsules is authorized for treatment of tuberculosis (TB) caused by *Mycobacterium tuberculosis*. It contains cycloserine as the active substance and it is given by oral route.

II. Risks associated with the medicine and activities to minimize or further characterize the risks.

Important risks of Cycloserine, together with measures to minimize such risks and the proposed studies for learning more about Cycloserine's risks, are outlined below.

Measures to minimize 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 authorized 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 minimize its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse events is collected continuously and regularly analyzed, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

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II.A List of important risks and missing information

Important risks of cycloserine 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 by patients. 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 cycloserine 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/use in special patient populations etc.).

List of important risks and missing Information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable

II.C Post-authorization development plan

No post-authorization study is planned for this product.

II.C.1 Studies which are conditions of the marketing authorization.

No studies are conditions of the marketing authorization or specific obligations of cycloserine.

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

Not applicable.