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SUMMARY OF THE SAFETY RISK MANAGEMENT PLAN (RMP)

Active substance	Telotristat ethyl
Product(s) concerned (brand name(s)):	Xermelo
MAH/Applicant name	Future Health Pharma GmbH

Data lock point for this module	27-August-2019
Version number of RMP when this module was last updated	5.1

Disclaimer: The Risk Management Plan (RMP) is a comprehensive document submitted as part of the application dossier for market approval of a medicine. The RMP summary contains information on the medicine's safety profile and explains the measures that are taken in order to further investigate and follow the risks as well as to prevent or minimise them.

The RMP summary of Xermelo is a concise document and does not claim to be exhaustive.

As the RMP is an international document, the summary might differ from the ”Arzneimittelinformation / Information sur le médicament” approved and published in Switzerland, e.g. by mentioning risks occurring in populations or indications not included in the Swiss authorization.

Please note that the reference document which is valid and relevant for the effective and safe use of Xermelo in Switzerland is the “Arzneimittelinformation / Information sur le médicament” (see www.swissmedic.ch) approved and authorized by Swissmedic.

Future Health Pharma GmbH is fully responsible for the accuracy and correctness of the content of the published summary RMP of Xermelo.

Summary of risk management plan for Xermelo (Telotristat Ethyl)

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

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

This summary of the RMP for Xermelo should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The medicine and what it is used for

Xermelo is authorised in combination with somatostatin analogue (SSA) therapy for the treatment of carcinoid syndrome diarrhoea in adult patients with metastatic neuroendocrine tumours (NETs; see SmPC for the full indication). It contains telotristat ethyl as the active substance and it is taken as a 250 mg film coated tablet, orally with food.

Further information about the evaluation of Xermelo's benefits can be found in Xermelo's EPAR, including in its plain-language summary, available on the European Medicines Agency website, under the medicine's webpage https://www.ema.europa.eu/en/medicines/human/EPAR/xermelo.

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

Important risks of Xermelo, together with measures to minimise such risks and the proposed activities for learning more about Xermelo'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 PL 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 Periodic Safety Update Report (PSUR) assessment, so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Xermelo is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Xermelo 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 Xermelo. 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);

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

There are no important identified risks, important potential risks or missing information for Xermelo.

II.B Summary of important risks

There are no important identified risks, important potential risks or missing information for Xermelo.

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 Xermelo.

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

There are no other studies required for Xermelo.