**Part VI – Summary of the risk management plan**

# Summary of risk management plan for Fynor 10,000 Ph.Eur. units, 25,000 Ph.Eur. units and 35,000 Ph.Eur units, gastro-resistant capsules hard (Pancreas powder)

This is a summary of the risk management plan (RMP) for Fynor 10,000 Ph.Eur. units, 25,000 Ph.Eur. units and 35,000 Ph.Eur units, gastro-resistant capsules hard (further to be referred to as Fynor). The RMP details important risks of Fynor, and how more information will be obtained about Fynor's risks and uncertainties (missing information).

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

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

## I. The medicine and what it is used for

Fynor is authorised in children, adolescents and adults for pancreatic enzyme replacement treatment in pancreatic exocrine insufficiency due to cystic fibrosis or other conditions (e.g. chronic pancreatitis, pancreatectomy, or pancreatic cancer) (see SmPC for the full indication). It contains pancreatin produced from porcine pancreatic tissue (as pancreas powder) as the active substance and the gastro-resistant capsules are taken orally.

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

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

Pancreas powder has been authorised for over 20 years, and the benefit-risk profile of the medicinal product is well established. Since this RMP concerns a well-established medicinal product and in line with the GVP Module V rev.2 as no additional pharmacovigilance activities or additional risk minimisation measures are in scope, no safety concerns are applicable.

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

### *II.B Summary of important risks*

As there are no important risks identified, this section is 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 Fynor.

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

There are no studies required for Fynor.