Part VI: Summary of the risk management plan

Summary of risk management plan for Zyfoqam

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

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

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

I. The medicine and what it is used for

Zyfoqam contains the active substance linagliptin which belongs to a group of medicines called "oral anti-diabetics". Oral anti-diabetics are used to treat high blood sugar levels. They work by helping the body reduce the level of sugar in the blood. Zyfoqam is used for 'type 2 diabetes' in adults, if the disease cannot be adequately controlled with one oral anti-diabetic medicine (metformin or sulphonylureas) or diet and exercise alone. Zyfoqam may be used together with other anti-diabetic medicines e.g. metformin, sulphonylureas (e.g. glimepiride, glipizide), empagliflozin, or insulin (see SmPC for the full indication). It contains linagliptin as the active substance and it is given by the oral route.

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

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

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

II.A List of important risks and missing information

Important risks of Zyfoqam 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 Zyfoqam. 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	• Pancreatitis
Important potential risks	• Pancreatic cancer
Missing information	• Pregnancy/breast-feeding

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 Zyfoqam.

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

There are no studies required for Zyfoqam.