Part VI: Summary of the risk management plan

Summary of risk management plan for Tidonalle (Teduglutide)

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

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

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

I. The medicine and what it is used for

Tidonalle is authorised for the treatment of patients 4 months corrected gestational age and above with Short Bowel Syndrome (SBS). Patients should be stable following a period of intestinal adaptation after surgery (see SmPC for the full indication). It contains Teduglutide as the active substance and it is given by subcutaneous route.

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

Important risks of Tidonalle, together with measures to minimise such risks and the proposed studies for learning more about Tidonalle'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 Tidonalle is not yet available, it is listed under 'missing information' below>

II.A List of important risks and missing information

Important risks of Tidonalle are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered.

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 Tidonalle. 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	• Biliary AEs • Pancreatic AEs • Cardiovascular AEs associated with fluid overload • GI stenosis and obstruction • GI stoma complications • Intestinal Polyps • Benign neoplasia of the GI tract including the hepatobiliary • system • Tumour promoting ability • Anxiety
Important potential risks	• AEs associated with increased absorption of oral concomitant medications • Local skin reactions • Potential for off-label use in patients with active Crohn's disease • Medication errors • Compromised nutritional status
Missing information	• Lack of experience for administration of teduglutide in subjects with severe, clinically unstable concomitant diseases, e.g., cardiovascular, respiratory, renal, infectious, endocrine, hepatic or CNS, or in patients with malignancies within the last 5 years • Lack of experience in pregnant or lactating women • Long-term safety in the paediatric population • Limited long-term safety data over 1 year of exposure • Lack of data in subjects with pre-existing severe hepatic impairment

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 Tidonalle.

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

There are no studies required for Tidonalle.