Summary of risk management plan for Fentasulan/Fentasublan sublingual tablets (Fentanyl)

This is a summary of the risk management plan (RMP) for Fentasulan/Fentasublan sublingual tablets, how these risks can be minimised, and how more information will be obtained about Fentasulan/Fentasublan risks and uncertainties (missing information).

Fentasulan/Fentasublan's summary of product characteristics (SmPC) and its package leaflet give essential information to Healthcare Professionals and patients on how Fentasulan/Fentasublan should be used.

I. The medicine and what it is used for

Fentasulan/Fentasublan is authorised for treatment for breakthrough pain in adult patients using opioid therapy for chronic cancer pain (see SmPC for the full indication). It contains fentanyl as the active substance, and it is given by sublingual route of administration.

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

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

II.A List of important risks and missing information

Important risks of Fentasulan/Fentasublan 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 Fentasulan/Fentasublan.

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	• Respiratory depression • Local tolerability • Misuse • Medication errors • Drug dependence • Drug abuse • Off-label use • Drug diversion • Overdose
Important potential risks	• Brain lesion • Cardiovascular depression • Accidental exposure • Serotonin syndrome induced by interaction between fentanyl and serotoninergic drugs
Missing information	• Limited information on use in children and adolescents • Limited use in women who are pregnant or breast-feeding women • Limited use in patients who have heart, kidney of liver • problems • Limited information on long-term use of fentanyl

II.B Summary of important risks

Respiratory depression	
Risk minimisation measures	Safety information in the SmPC: Section 4.3, section 4.4, section 4.5, section 4.6, section 4.8 and 5.1. Safety information in the PL: Section 2, section 3 and section 4. Legal status: prescription only medicine Additional risk minimisation measures: Healthcare professional guide Patient/carer guide

Local tolerability	
Risk minimisation measures	Safety information in the SmPC: Section 4.3, section 4.4, section 4.8. Safety information in the PL: Section 2, and section 4. Legal status: prescription only medicine Additional risk minimisation measures: Not applicable

Misuse	
Risk minimisation measures	Routine risk minimisation measures Safety information in the SmPC: Section 4.2. Safety information in the PL: Section 3. Legal status: prescription only medicine Additional risk minimisation measures: Healthcare professional guide Patient/carer guide

Medication errors	
Risk minimisation measures	Routine risk minimisation measures Safety information in the SmPC: Section 4.2. Safety information in the PL: Section 3. Legal status: prescription only medicine Additional risk minimisation measures: Healthcare professional guide Patient/carer guide

Drug dependence	
Risk minimisation measures	Routine risk minimisation measures Safety information in the SmPC: Section 4.4, section 4.6, section 4.8 and section 5.1 Safety information in the PL: Section 3 and section 4. Legal status: prescription only medicine Additional risk minimisation measures: Healthcare professional guide Patient/carer guide

Drug abuse	
Risk minimisation measures	Routine risk minimisation measures Safety information in the SmPC: Section 4.4, section 4.8 and section 4.9 Safety information in the PL: Section 3 and section 4. Legal status: prescription only medicine Additional risk minimisation measures: Healthcare professional guide Patient/carer guide

Off-label use	
Risk minimisation measures	Routine risk minimisation measures Safety information in the SmPC: Section 4.2. Safety information in the PL: Section 3. Legal status: prescription only medicine Additional risk minimisation measures: Healthcare professional guide Patient/carer guide

Drug diversion	
Risk minimisation measures	Routine risk minimisation measures Safety information in the SmPC: Section 4.2, Safety information in the PL: Section 3. Other routine risk minimisation measures beyond the PI Tablet formulation designed to dissolve rapidly when placed under the tongue. Legal status: prescription only medicine Additional risk minimisation measures: Healthcare professional guide Patient/carer guide

Overdose	
Risk minimisation measures	Routine risk minimisation measures Safety information in the SmPC: Section 4.4, section 4.8 and section 4.9 Safety information in the PL: Section 3 Legal status: prescription only medicine Additional risk minimisation measures: Healthcare professional guide Patient/carer guide

Brain lesion	
Risk minimisation measures	Routine risk minimisation measures Safety information in the SmPC: Section 4.3 Safety information in the PL: Section 1 Legal status: prescription only medicine Additional risk minimisation measures: Not applicable

Cardiovascular depression	
Risk minimisation measures	Routine risk minimisation measures Safety information in the SmPC: Section 4.4, section 4.8, section 4.9, and section 5.1 Safety information in the PL: Section 2 and section 4 Legal status: prescription only medicine Additional risk minimisation measures: Not applicable

Accidental exposure	
Risk minimisation measures	Routine risk minimisation measures Safety information in the SmPC: Section 4.4 and section 4.8. Safety information in the PL: Section 4 and section 5. Legal status: prescription only medicine Additional risk minimisation measures: Healthcare professional guide Patient/carer guide

Serotonin syndrome induced by interaction between fentanyl and serotoninergic drugs	
Risk minimisation measures	Routine risk minimisation measures Safety information in the SmPC: Section 4.4 and section 4.5 Safety information in the PL: Section 2 Legal status: prescription only medicine Additional risk minimisation measures: Healthcare professional guide Patient/carer guide

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 Fentasulan/Fentasublan sublingual tablets.

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

There are no studies required for Fentasulan/Fentasublan sublingual tablets.