Part VI: Summary of the risk management plan

Summary of risk management plan Tramadol/Paracetamol Accord 37.5/325 mg Effervescent Tablets (Tramadol hydrochloride/ Paracetamol)

This is a summary of the risk management plan (RMP) for Tramadol/Paracetamol Accord Effervescent Tablets. The RMP details important risks of Tramadol/Paracetamol Accord Effervescent Tablets, how these risks can be minimised, and how more information will be obtained about Tramadol/Paracetamol Accord Effervescent Tablets and uncertainties (missing information).

Tramadol/Paracetamol Accord Effervescent Tablet's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Tramadol/Paracetamol Accord Effervescent Tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Tramadol/Paracetamol Accord Effervescent Tablet's RMP.

I. The medicine and what it is used for

Tramadol/Paracetamol Accord effervescent tablets are indicated for the symptomatic treatment of moderate to severe pain.

The use of tramadol hydrochloride/paracetamol should be restricted to patients whose moderate to severe pain is considered to require a combination of tramadol hydrochloride and paracetamol.

It contains tramadol hydrochloride and paracetamol as the active substances, and it is given by oral route.

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

Important risks of Tramadol/Paracetamol Accord Effervescent Tablets, together with measures to minimise such risks and the proposed studies for learning more about Tramadol/Paracetamol Accord Effervescent Tablets' 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 analyzed, 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 Tramadol/Paracetamol Accord Effervescent Tablets are not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Tramadol/Paracetamol Accord Effervescent Tablets 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 Tramadol/Paracetamol Accord Effervescent Tablets. 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).

Important identified risks	• Convulsion

	• Psychical and/or physical dependence (included dependence, abuse, misuse and withdrawal syndrome)
Important potential risks	• Foetal and neonatal risk after drug exposure during pregnancy and breastfeeding
Missing Information	• Use in children below 12 years of age

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 authorization or specific obligation of Tramadol/Paracetamol Accord Effervescent Tablets.

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

There are no studies required for Tramadol/Paracetamol Accord Effervescent Tablets as post-authorisation development plan.