Part VI: Summary of the risk management plan

Summary of risk management plan for Dolergot DUO 37,5mg/325mg film coated tables (Tramadol/Paracetamol).

This is a summary of the risk management plan (RMP) for Tramadol/Paracetamol Dolergot DUO 37.5 mg/325 mg film coated tablets (hereinafter referred to as Dolergot DUO). The RMP details important risks of Dolergot DUO and how more information will be obtained about Dolergot DUO risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Dolergot DUO RMP.

I. The medicine and what it is used for

Dolergot DUO is authorised for the symptomatic treatment of moderate to severe pain (see SmPC for the full indication). It contains Tramadol/Paracetamol as the active substances and it is given for oral route.

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

Important risks of Tramadol/Paracetamol Dolergot DUO, together with measures to minimise such 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 Dolergot DUO is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Tramadol/Paracetamol Dolergot DUO 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 Dolergot DUO. 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	• Convulsion, epilepsy and seizures in patients with predisposition to convulsive disorders • Psychical and/or physical dependence (included dependence, abuse, misuse and withdrawal syndrome) • Severe cutaneous adverse reactions (included Toxic epidermal necrolysis, Stevens - Johnson syndrome) • Hepatotoxicity • Serotonin syndrome due to concomitant treatment with serotonergic drugs • Use in patients with renal and/or liver impairment
Important potential risks	• Foetal and neonatal risk after drug exposure during pregnancy and breastfeeding • Overdose (non-intentional and intentional)
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 authorisation or specific obligation of Tramadol/Paracetamol Dolergot DUO.

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

There are no studies required for Tramadol/Paracetamol Dolergot DUO.