# Summary of risk management plan for Tramadol/Paracetamol Pharmacons

This is a summary of the risk management plan (RMP) for Tramadol/Paracetamol Pharmacons. The RMP details important risks of Tramadol/Paracetamol Pharmacons and how more information will be obtained about Tramadol/Paracetamol Pharmacons 's risks and uncertainties (missing information).

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

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

## I. The medicine and what it is used for

Tramadol/Paracetamol Pharmacons is authorised for the symptomatic treatment of moderate to severe pain in adults and adolescents over the age of 12 year (see SmPC for the full indication). It contains tramadol+paracetamol as the active substance and it is given by film-coated tablets tramadol 37.5 mg/paracetamol 325 mg and tramadol 75 mg/paracetamol 650 mg

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

Important risks of Tramadol/Paracetamol Pharmacons, together with measures to minimise such risks and the proposed studies for learning more about Tramadol/Paracetamol Pharmacons '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*.

## *II.A List of important risks and missing information*

Important risks of Tramadol/Paracetamol Pharmacons 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 Pharmacons. 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 | Not applicable |
| Important potential risks | Not applicable |
| Missing information | Not applicable |

## *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 Pharmacons.

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

There are no studies required for Tramadol/Paracetamol Pharmacons.