

## Part VI: Summary of the risk management plan

### Summary of risk management plan for CORYFINORO Influenza e Raffreddore 600 mg/10 mg granulato in bustina (Paracetamol/Phenylephrine hydrochloride)

This is a summary of the risk management plan (RMP) for CORYFINORO Influenza e Raffreddore 600 mg/10 mg granulato in bustina. The RMP details important risks of CORYFINORO Influenza e Raffreddore 600 mg/10 mg granulato in bustina, how these risks can be minimised, and how more information will be obtained about CORYFINORO Influenza e Raffreddore 600 mg/10 mg granulato in bustina's risks and uncertainties (missing information).

CORYFINORO Influenza e Raffreddore 600 mg/10 mg granulato in bustina's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how CORYFINORO Influenza e Raffreddore 600 mg/10 mg granulato in bustina should be used.

Important new concerns or changes to the current ones will be included in updates of CORYFINORO Influenza e Raffreddore 600 mg/10 mg granulato in bustina's RMP.

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

CORYFINORO Influenza e Raffreddore 600 mg/10 mg granulato in bustina is indicated in the short-term treatment of cold and flu symptoms, including mild to moderate pain and fever, when associated with nasal congestion. It contains paracetamol and phenylephrine hydrochloride as 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 CORYFINORO Influenza e Raffreddore 600 mg/10 mg granulato in bustina, 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*.

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

Important risks of CORYFINORO Influenza e Raffreddore 600 mg/10 mg granulato in bustina 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 CORYFINORO Influenza e Raffreddore 600 mg/10 mg granulato in bustina. 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).

<b>List of important risks and missing information</b>	
Important identified risks	None
Important potential risks	None
Missing information	None