

## **PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN**

## Summary of risk management plan for **Levonorgestrel Naari** (**Levonorgestrel**)

This is a summary of the risk management plan (RMP) for **Levonorgestrel Naari**. The RMP details important risks of **Levonorgestrel Naari**, how these risks can be minimised and how more information will be obtained about **Levonorgestrel Naari**'s risks and uncertainties (missing information).

**Levonorgestrel Naari**'s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how **Levonorgestrel Naari** should be used.

Important new concerns or changes to the current ones will be included in updates of **Levonorgestrel Naari**'s RMP.

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

**Levonorgestrel Naari** is authorised for emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method (see SmPC for the full indication). It contains levonorgestrel as active substance 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 **Levonorgestrel Naari**, together with measures to minimise such risks and the proposed studies for learning more about **Levonorgestrel Naari**'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 **Levonorgestrel Naari** 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 **Levonorgestrel Naari**. 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>Summary of safety concerns</b>	
Important identified risks	- None
Important potential risks	- None
Missing information	- None

### ***II.B Summary of important risks***

No important identified and potential risks or missing information were identified for the medicinal product **Levonorgestrel Naari, 1,5 mg, tablet**.

## ***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 **Levonorgestrel Naari**.

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

There are no studies required for **Levonorgestrel Naari**.