

Part VI: Summary of the risk management plan

Summary of risk management plan of Naloxone Accord 400 micrograms/ml solution for injection/infusion in pre-filled syringe (naloxone hydrochloride)

This is a summary of the risk management plan (RMP) for Naloxone Accord 400 micrograms/ml solution for injection/infusion in pre-filled syringe. The RMP details important risks of Naloxone Accord 400 micrograms/ml solution for injection/infusion in pre-filled syringe, how these risks can be minimised, and how more information will be obtained about Naloxone Accord 400 micrograms/ml solution for injection/infusion in pre-filled syringe's risks and uncertainties (missing information).

Naloxone Accord 400 micrograms/ml solution for injection/infusion in pre-filled syringe's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on Naloxone Accord 400 micrograms/ml solution for injection/infusion in pre-filled syringe should be used.

Important new concerns or changes to the current ones will be included in updates of Naloxone Accord 400 micrograms/ml solution for injection/infusion in pre-filled syringe's RMP.

I. The medicine and what it is used for

Naloxone Accord 400 micrograms/ml solution for injection in pre-filled syringe is indicated for:

- Complete or partial reversal of CNS and especially respiratory depression, caused by natural or synthetic opioids.
- Diagnosis of suspected acute opioid overdose or intoxication.
- Complete or partial reversal of respiratory and other CNS depression in the neonate whose mothers have received opioids.

Naloxone Accord 400 micrograms/ml solution for injection/infusion in pre-filled syringe should only be administered by a healthcare professional.

It contains naloxone as the active substance and it can be injected intravenously (i.v.) or intramuscularly (i.m.) or can be given via intravenous infusion.

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

Important risks of Naloxone Accord 400 micrograms/ml solution for injection/infusion in pre-filled syringe together with measures to minimise such risks and the proposed studies for learning more about Naloxone Accord 400 micrograms/ml solution for injection/infusion in pre-filled syringe' 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 including signal management activity, 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 Naloxone Accord 400 micrograms/ml solution for injection/infusion in pre-filled syringe are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. 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 Naloxone Accord 400 micrograms/ml solution for injection/infusion in pre-filled syringe. 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).

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| Important identified risks | <ul style="list-style-type: none"> • Precipitation of acute opioid withdrawal effects • Delayed respiratory depression due to short half-life of naloxone • Lack of effect in mixed overdose (concomitant overdose of non-opioid drugs) |
| Important potential risks | <ul style="list-style-type: none"> • None |
| Missing information | <ul style="list-style-type: none"> • None |

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 Naloxone Accord 400 micrograms/ml solution for injection/infusion in pre-filled syringe.

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

There are no studies required for Naloxone Accord 400 micrograms/ml solution for injection/infusion in pre-filled syringe as post-authorisation development plan.