**PACKAGE LEAFLET**

**Package leaflet: Information for the patient**

**Naloxone Hydrochloride Accord 400 micrograms/ml solution for injection/infusion in pre-filled syringe**
naloxone hydrochloride

**Read all of this leaflet carefully before this medicine is administered to you because it contains important information for you.**
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

**What is in this leaflet:**


## 1. What Naloxone Hydrochloride Accord is and what it is used for

Naloxone Hydrochloride Accord is a drug used to counter the effects of opioid overdose, for example morphine overdose.

Naloxone Hydrochloride Accord is used for reversal of unwanted effects of opioids for countering life-threatening depression of the central nervous system and respiratory system (breathing difficulties).

Naloxone Hydrochloride Accord is also used to diagnose an acute opioid overdose or intoxication.

If a woman was given analgetic drugs during labour, a newborn child can be treated with Naloxone Hydrochloride Accord for reversal of unwanted effects of opioids, e.g. if he/she suffers from breathing problems or depression of central nervous system.

Naloxone Hydrochloride Accord pre-filled syringe should not be used in infants weighing less than 4 kg.

## 2. What you need to know before Naloxone Hydrochloride Accord is administered to you

Naloxone Hydrochloride Accord must not be administered:
- if you are **allergic (hypersensitive)** to naloxone hydrochloride or to any of the ingredients of this medicine (listed in section 6).

Naloxone Hydrochloride Accord pre-filled syringe should not be used in infants weighing less than 4 kg.

**Warnings and precautions**
Talk to your doctor or pharmacist before Naloxone Hydrochloride Accord is administered to you:
Special care will be taken
- If you are **physically dependent to opioids** (for example morphine) or have received high doses of these drugs (you may get strong withdrawal symptoms after receiving Naloxone

Hydrochloride Accord because of a too rapid reversal of the opioid effect; these symptoms may be high blood pressure, palpitations, severe difficulties in breathing or cardiac arrest).
- If you have any **heart or circulation problems** (because side effects like high or low blood pressure, palpitations or severe difficulties in breathing may appear more likely).

**Other medicines and Naloxone Hydrochloride Accord**
Tell your doctor or pharmacist if you are taking or have recently taken any other medicines:
- If you are taking **painkilling medication** like **buprenorphine**. The painkilling effect may even become stronger while you are treated with Naloxone Hydrochloride Accord. However, the reversal of unwanted effects, like respiratory depression caused by buprenorphine is limited.
- If you are taking **sedatives**, as Naloxone Hydrochloride Accord may possibly have a less rapid effect.
- If you are taking any medication that may affect your **heart or circulation** (e.g. antihypertensive drugs e.g. clonidine), even those not prescribed.

**Naloxone Hydrochloride Accord with alcohol**
Please inform your doctor if you drank alcohol. In patients with multi-intoxication (with opioids and sedatives or alcohol) Naloxone Hydrochloride Accord may have a less rapid effect.

**Pregnancy and breastfeeding**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

*Pregnancy*
There is no adequate information available regarding the use of Naloxone Hydrochloride Accord in pregnant women. During pregnancy, your doctor will outweigh the benefit of Naloxone Hydrochloride Accord against possible risks to the unborn baby. Naloxone Hydrochloride Accord can cause withdrawal symptoms in the newborn baby.

*Breast-feeding*
It is not known whether Naloxone Hydrochloride Accord passes into breast milk and it has not been established whether infants who are breast-fed are affected by Naloxone Hydrochloride Accord. Therefore, breast-feeding is not recommended for 24 hours after treatment.

**Driving and using machines**
After receiving Naloxone Hydrochloride Accord for the reversal of the effects of opioids you must not take part in road traffic, operate machinery or engage in any other physically or mentally demanding activity for at least 24 hours since the effects of opioids may possibly recur.

**Naloxone Hydrochloride Accord contains sodium**
This medicine contains less than 1 mmol sodium (23 mg) per 1 ml dose, that is to say essentially "sodium-free".

## 3. How Naloxone Hydrochloride Accord is administered

The recommended doses given to you are:

<u>Reversal of the unwanted effects of opioids</u>
Adults: 100-200 micrograms, if necessary additional injections of 0.1 mg may be given
Children: 100-200 micrograms per kg body weight, if necessary additional injections of the same dose may be given

<u>Diagnosis and treatment of opioid overdose or intoxication:</u>
Adults: 400 micrograms – 2 mg, if necessary the injections can be repeated at intervals of 2-3 minutes. The maximum dose of 10 mg should not be exceeded.

Children: 10 micrograms per kg body weight, if an additional dose is necessary, the dose can be increased in the next injection to 100 micrograms/kg

Reversal of the unwanted effects of opioids in neonates whose mothers have received opioids*:*
10 micrograms per kg body weight, if necessary additional injections may be given.

For reversal of the unwanted effects of opioids (in adults, children and also in neonates) patients are monitored to ensure that the desired effect of Naloxone Hydrochloride Accord occurs. Additional doses may be given every 1 – 2 hours if necessary.

In elderly patients with heart or circulation problems or in those receiving medicines that can produce heart or circulation disorders (e.g. cocaine, methamphetamine, cyclic antidepressants, calcium channel blockers, beta-blockers, digoxin) Naloxone Hydrochloride Accord will be used with caution since serious side effects such as fast heart beat (ventricular tachycardia) and fibrillation have occurred.

Naloxone Hydrochloride Accord pre-filled syringe should not be used in infants weighing less than 4 kg.

If you have the impression that the effect of Naloxone Hydrochloride Accord is too strong or too weak, talk to your doctor.

**Method of administration**
Naloxone Hydrochloride Accord will be given to you always by intravenous or intramuscular injection (into a vein or into a muscle) or, after dilution, as intravenous infusion (over a longer period).
Naloxone Hydrochloride Accord will be given by your anaesthetist or experienced physician.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

It may be difficult to know what side effects Naloxone Hydrochloride Accord has, because it is always given after other drugs have also been used.

**The following side effects may be serious. If any of the following side effects occur, consult a doctor immediately:**

*Common (may affect up to 1 in 10 people):*
- Fast heart beat

*Uncommon* (may affect up to 1 in 100 people):
- Changes in the way your heart beats, slow heart rate

*Rare (may affect up to 1 in 1,000 people):*
- Seizures

Very rare (may affect up to 1 in 10,000 people):
- Allergic reactions (nettle rash, nasal catarrh or a cold, difficult breathing, Quincke's oedema (giant swelling)), allergic shock
- Fibrillation, cardiac arrest
- Fluids on the lungs (pulmonary oedema)

Other side effects include:

*Very common (may affect more than 1 in 10 people):*
- Nausea

*Common (may affect up to 1 in 10 people):*
- Dizziness, headache
- Increased or decreased blood pressure (you may have a headache or feel faint)
- Vomiting
- If a too large dose is given after an operation, you may become excited and feel pain (because the painkilling effects of the medicines you were given will have been counteracted as well as the effects on your breathing).

Uncommon (may affect up to 1 in 100 people)
- Involuntary trembling or quivering (tremor), sweating
- Diarrhoea, dry mouth
- Over breathing (hyperventilation)
- Irritation of vessel wall has been reported after i.v. administration; local irritation and inflammation have been reported after i.m. administration.

*Rare* (may affect up to 1 in 1,000 people):
- Tension

*Very rare* (may affect up to 1 in 10,000 people):
- Discoloration and lesions of the skin (erythema multiforme)

**Reporting of side effects**
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly HPRA Pharmacovigilance; Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Naloxone Hydrochloride Accord

Keep this medicine out of the sight and reach of children.

You should not be given Naloxone Hydrochloride Accord after the expiry date which is stated on the box (Twist box) and syringe label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special temperature storage conditions.
Keep the syringe in the outer box in order to protect from light.

Shelf-life after first opening
After first opening the medicinal product should be used immediately.

Shelf-life after dilution
Chemical and physical in-use stability has been demonstrated for 36 hours at 2 to 8 °C and at 25°C. From the microbiological point of view, the dilutions should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

Do not use this medicine if you notice discolouration of solution or visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

**What Naloxone Hydrochloride Accord contains**

The active substance is naloxone hydrochloride dihydrate. Each 1 ml pre-filled syringe contains 400 micrograms naloxone hydrochloride (as dihydrate).

The other ingredients are: sodium chloride, hydrochloric acid, concentrated (for pH adjustment) and water for injections.

**What Naloxone Hydrochloride Accord looks like and contents of the pack**

Naloxone Hydrochloride Accord is a clear and colourless solution for injection/infusion in pre-filled syringe, practically free from foreign particles.

1 ml clear glass pre-filled syringe with tip cap, plunger stopper (grey bromobutyl rubber stopper) and plunger rod (polypropylene). Graduations per 0.1 mL are present on the barrel of the syringe.

The pre-filled syringe is supplied with needle (23 G; 30 mm), packaged in an outer box (Twist Box).

Pack sizes: one pre-filled syringe and one needle.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder**
Accord Healthcare Ireland Limited
Euro House
Euro Business Park
Little Island
Cork T45 K857
Ireland

**Manufacturer**
Accord Healthcare Polska Sp.z o.o.
ul. Lutomierska 50,
95-200 Pabianice
Poland

Or
Accord Healthcare B.V.
Winthontlaan 200, 3526KV Utrecht
The Netherlands

Or

Laboratori Fundació Dau
C/ C, 12-14 Pol. Ind.
Zona Franca, Barcelona, 08040, Spain

**This medicine is authorised in the Member States of the European Economic Area under the followings names:**

| Name of Member State | Name of Medicinal Product |
|---|---|
| Austria | Naloxone Accord 400 Mikrogramm/ml Injektions-/Infusionslösung in einer Fertigspritze |

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|---|---|
| Belgium | Naloxone Accord 400 microgrammes/ml / microgram/ml /Mikrogramm/ml Solution injectable/pour perfusion en seringue préremplie / Oplossing voor injectie / infusie in een voorgevulde spuit / Injektions-/Infusionslösung in einer Fertigspritze |
| Germany | Naloxon Accord 400 Mikrogramm/ml Injektions-/Infusionslösung in einer Fertigspritze |
| Denmark | Naloxonhydrochlorid Accord |
| Finland | Naloxone Accord 400 mikrog/ml Injektio-/infuusioneste, liuos, esitäytetty ruisku |
| Netherlands | Naloxone Accord 400 microgram/ml Oplossing voor injectie / infusie in een voorgevulde spuit |
| Norway | Naloxone Accord |
| Sweden | Naloxone Accord 0.4 mg/ml Injektions- / infusionsvätska, lösning i förfylld spruta |
| Spain | Naloxone Accord 400 microgramos/ml solución inyectable y para perfusión en jeringa precargada |
| Portugal | Naloxone Accord |
| Italy | Naloxone Accord |
| France | Naloxone Accord 400 microgrammes/ml, Solution injectable/pour perfusion en seringue préremplie |
| Ireland | Naloxone Hydrochloride Accord 400 micrograms/ml solution for injection/infusion in pre filled syringe |
| Poland | Naloxone Accord |
| Czech Republic | Naloxone Accord |

**This leaflet was last revised in January 2023**

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**The following information is intended for healthcare professionals only:**

Shelf-life after first opening and after dilution: see section 5.

For i.v. infusion, Naloxone Hydrochloride Accord is diluted with sodium chloride 9 mg/ml (0.9 %) solution or glucose 50 mg/ml (5 %) solution. 5 pre-filled syringes of Naloxone Hydrochloride Accord (2 mg) per 500 ml give concentration of 4 micrograms/ml.

It is recommended that infusions of Naloxone Hydrochloride Accord should not be mixed with preparations containing bisulphite, metabisulphite, long-chain or high-molecular-weight anions, or solutions with an alkaline pH.

This medicinal product is for single use only.

Please inspect the medicinal product visually prior to use (also after dilution). Use only clear and colourless solutions practically free from particles.