Approved Patient Information Leaflet for Naloxone HCl Fresenius

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

NALOXONE HCl 0,4 mg/1 ml FRESENIUS solution for injection

NALOXONE HCl NEONATAL 0,02 mg/1 ml FRESENIUS solution for injection

Naloxone hydrochloride

Sugar free.

Read all of this leaflet carefully before you or your baby is given NALOXONE HCl FRESENIUS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

What is in this leaflet

1. What NALOXONE HCl FRESENIUS is and what it is used for
2. What you need to know before you or your baby is administered NALOXONE HCl FRESENIUS
3. How NALOXONE HCl FRESENIUS is given
4. Possible side effects
5. How to store NALOXONE HCl FRESENIUS

6. Contents of the pack and other information.

1. What NALOXONE HCl FRESENIUS is and what it is used for

NALOXONE HCl FRESENIUS belongs to a group of medicines called opioid antagonists.

Naloxone hydrochloride, as in NALOXONE HCl FRESENIUS, reverses the effect of opium-like substances like morphine, heroin, codeine and methadone.

It is used to treat people who have received an overdose of opioid-like substances.

It may be used to reverse the effects of powerful painkillers used on you during surgery once the need for the pain control is no longer required.

It may be given to your newly born baby if you have received an opioid-type medicine during labour.

2. What you need to know before you or your baby is administered NALOXONE HCl FRESENIUS

You or your baby should not be administered NALOXONE HCl FRESENIUS:

- if you or your baby is hypersensitive (allergic) to naloxone hydrochloride or any of the other ingredients of NALOXONE HCl FRESENIUS (listed in section 6).

Warnings and precautions

Special care should be taken with NALOXONE HCl FRESENIUS:

- if you are breastfeeding or pregnant
- if you are addicted to any medicines or physically dependent on opioids (for example morphine) or have received high doses of these medicines (you may get strong withdrawal symptoms after receiving NALOXONE HCl FRESENIUS because of a rapid reversal of the

opioid effect; these symptoms may be high blood pressure, palpitations, severe difficulties in breathing or cardiac arrest)

- if you or your baby have any heart or circulatory problems (because side effects like high or low blood pressure, palpitations or severe difficulties in breathing may be more likely to appear)
- if you or your baby has a lung disease
- if you or your baby has a liver disease
- if you or your baby has a kidney disease.

Other medicines and NALOXONE HCl FRESENIUS

Always tell your health care provider if you or your baby are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines and NALOXONE HCl FRESENIUS may interfere with each other; this includes medications for heart muscle damage (cardiotoxic medicines).

Tell your doctor if you or your baby is taking:

- sedatives or alcohol, as NALOXONE HCl FRESENIUS may possibly have a less rapid effect
- strong painkillers like buprenorphine and pentazocine
- medicines that may affect heart or blood circulation (e.g., antihypertensive medicines, such as clonidine), even those not prescribed.

NALOXONE HCl FRESENIUS with food, drink and alcohol

Please inform your doctor if you drank alcohol. In patients with multi-intoxication (with opioids and sedatives or alcohol) NALOXONE HCl FRESENIUS may have a less rapid effect.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving NALOXONE HCl FRESENIUS.

Driving and using machines

After receiving NALOXONE HCl FRESENIUS for the reversal of the effects of opioids, you must not drive a vehicle, operate machinery or engage in any other physically or mentally demanding activity for at least 24 hours, as the effects of opioids may possibly recur.

NALOXONE HCl FRESENIUS contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially sodium free.

3. How NALOXONE HCl FRESENIUS is given

You will not be expected to give yourself NALOXONE HCl FRESENIUS. It will be given to you or your baby by a person who is qualified to do so.

Your doctor will decide what your or your baby's dose is and for how long you or your baby will receive NALOXONE HCl FRESENIUS. This will vary from patient to patient. It will depend on your or your baby's condition and other factors, such as your physical condition, body mass, age, as well as other medicines that you or your baby is taking at the time or after.

For most conditions, NALOXONE HCl FRESENIUS is given as a single dose that may be repeated after a two-to-three-minute interval.

As NALOXONE HCl FRESENIUS is administered under controlled conditions and the effects thereof are closely monitored, the likelihood of overdosage is extremely rare.

NALOXONE HCl FRESENIUS solution for injection is administered either

- directly under the skin (subcutaneously)
- directly into your muscle (intramuscularly)
- directly into the vein (intravenously)
- or as a slow intravenous infusion directly into your vein.

If you or your baby receives more Naloxone HCl Fresenius than you should

Since a health care provider will administer NALOXONE HCl FRESENIUS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you a miss a dose of NALOXONE HCl FRESENIUS

Since a health care provider will administer NALOXONE HCl FRESENIUS, it is unlikely that the dose will be missed.

4. Possible side effects

NALOXONE HCl FRESENIUS can have side effects.

Not all side effects reported for NALOXONE HCl FRESENIUS are included in this leaflet. Should your or your baby's general health worsens or if you or your baby experiences any untoward

effects while being given NALOXONE HCl FRESENIUS, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop receiving NALOXONE HCl FRESENIUS and tell your doctor immediately:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you or your baby has them, you or your baby may have had a serious reaction to NALOXONE HCl FRESENIUS. You or your baby may need urgent medical attention.

Tell your doctor immediately if you notice any of the following:

- sweating
- involuntary trembling or quivering (tremor)
- increased heart rate, irregular heart rate
- nervousness or restlessness
- irritability
- change in behaviour or agitation
- seizures
- slow heart rate
- complete stoppage of the heart
- shortness of breath due to the accumulation of fluid on your lungs.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- dizziness, headache
- changes in your blood pressure, increased or decreased blood pressure (you may have a headache or feel faint)
- nausea (feeling sick), vomiting (being sick)
- if too large a 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).

Less frequent side effects:

- tension
- diarrhoea, dry mouth
- abnormally rapid and deep breathing (hyperventilation)
- irritation of the blood vessel wall has been reported after IV administration.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects:

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects via the **Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of NALOXONE HCl FRESENIUS.

Health care providers are asked to report any suspected Adverse Drug Reactions to the Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com, and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store NALOXONE HCl FRESENIUS

- Store all medicines out of reach of children.
- NALOXONE HCl FRESENIUS will be stored in the pharmacy or in the hospital wards. The injection is protected from light, and kept in a cool place at a temperature at or below 25 °C.

6. Contents of the pack and other information

The active substance is naloxone hydrochloride.

NALOXONE HCl 0,4 mg/1 ml FRESENIUS: Each 1 ml ampoule contains 0,4 mg naloxone hydrochloride.

NALOXONE HCl NEONATAL 0,02 mg/1 ml FRESENIUS: Each 2 ml ampoule contains 0,04 mg naloxone hydrochloride.

The other ingredients are methylparaben (which acts as a preservative), glacial acetic acid (for pH-adjustment), sodium acetate trihydrate, sodium chloride and water for injection.

What NALOXONE HCl FRESENIUS looks like and contents of the pack:

NALOXONE HCl 0,4 mg/1 ml FRESENIUS: 1 ml OPC type I amber glass ampoules packed in boxes of 10.

NALOXONE HCl NEONATAL 0,02 mg/1 ml FRESENIUS: 2 ml OPC type I amber glass ampoules packed in boxes of 10.

A clear, colourless solution.

Holder of Certificate of Registration and Manufacturer:

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten 6020

Gqeberha

South Africa

Tel: +27 (0)41 403 1600

This leaflet was last revised in

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Registration numbers

NALOXONE HCl 0,4 mg/1 ml FRESENIUS:	27/1.4/0157
NALOXONE HCl NEONATAL 0,02 mg/1 ml FRESENIUS:	27/1.4/0158