Date: 08/06/2026

ARABIAN OASIS
واحة العرب

Direct Healthcare Professional Communication (DHPC)

NALOXONE: Presence of Foreign Language on the Outer Packaging and Package Leaflet of a Specific Batch

Dear Healthcare Professionals,

Greetings,
This information is being communicated by Galenica Senese Pharmaceutical Industry Srl in agreement with the Saudi Food and Drug Authority (SFDA). With reference to a quality report received regarding the packaging and leaflet language of Naloxone (Batch No. 25C21), manufactured by Galenica Senese, and following review of the affected batch information, we would like to inform you of the following:

Summary:

It has been reported that the outer packaging and internal leaflet of the affected batch include information in a foreign language. To ensure clarity of information for healthcare professionals and safe and effective use of the product, the English Patient Information Leaflet is provided in Annex 1 of this DHPC.
Based on the information received, an English sticker is available on the pack and the English leaflet is supplied with each delivery.

Further information on the Safety concern and recommendations:

- The issue relates to the availability and clarity of product information due to the presence of foreign-language information on the outer packaging and internal leaflet of the affected batch.
- No new safety concern has been identified from this quality notification. The purpose of this communication is to ensure that healthcare professionals have access to the English leaflet and the required product information.
- The English Patient Information Leaflet is attached in Annex 1 and should be used as the reference for product information for the affected batch.

Recommendations:

- All healthcare professionals are kindly requested to refer to the English version of the Patient Information Leaflet provided in Annex 1 to ensure that all necessary information is clearly communicated for safe and effective use.
- Healthcare institutions are requested to ensure that the English leaflet is available to relevant healthcare professionals handling or administering the affected batch.
- If you require more details regarding this batch, please contact Arabian Oasis for Development and Commercial Investment Company at 0548365798 or via email at Regulatory@aodci.com.sa.
- If you notice any packaging or leaflet with unclear or missing information for any other batch, please report it immediately to the SFDA reporting system: https://ade.sfda.gov.sa/Home/Report.

Attachments:

- Please refer to the Patient Information Leaflet provided in Annex 1.

Call for Reporting

If you experience any adverse events or have concerns related to Naloxone, please report via:

- Local company contact: Arabian Oasis for Development and Commercial Investment Company, Tel: 0548365798, Email: Regulatory@aodci.com.sa
- National Pharmacovigilance Center (NPC) - Saudi Food & Drug Authority (SFDA): Call Center: 19999, Email: npc.drug@sfda.gov.sa Website: https://ade.sfda.gov.sa.

We appreciate your commitment to patient safety and quality care, and we thank you for your continued cooperation.
Sincerely,
Arabian Oasis for Development and Commercial Investment Company

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA

ANNEX 1

Package leaflet: information for the user

NALOXONE HYDROCHLORIDE GALENICA SENESE adults 0.4 mg/ml solution for injection

NALOXONE HYDROCHLORIDE GALENICA SENESE children 0.04 mg/2ml solution for injection

Naloxone hydrochloride

Equivalent medicine

Read this leaflet carefully before you start using this medicine 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, pharmacist or nurse.

This medicine has been prescribed for you only. Do not pass it on to others, even if their symptoms are the same as yours. It may be harmful.

- If you get any side effects, including any not listed in this leaflet, talk to your doctor, pharmacist, or nurse. See section 4.

Contents of this sheet:

1. What is NALOXONE HYDROCHLORIDE GALENICA SENESE and what is it used for?

NALOXONE HYDROCHLORIDE GALENICA SENESE contains the active ingredient naloxone hydrochloride dihydrate, a drug

belonging to the class of opioid antagonists. It works by blocking the activity of opium derivatives, such as morphine and heroin.

NALOXONE HYDROCHLORIDE GALENICA SENESE adults is used to counteract the effects of acute

intoxication due to overdose of opium derivatives (analgesics, narcotics).

NALOXONE HYDROCHLORIDE GALENICA SENESE children 0.04 mg/2 ml is indicated for respiratory depression in the

newborn caused by maternal exposure to opium derivatives before birth.

This medicine is used only in emergency cases and by specialized medical personnel.

2. What you need to know before using NALOXONE HYDROCHLORIDE GALENICA SENESE Do not use

NALOXONE HYDROCHLORIDE GALENICA SENESE

- if you are allergic to naloxone or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using NALOXONE HYDROCHLORIDE GALENICA SENESE.

Symptoms of acute opioid intoxication (overdose) are:

- irregular and sometimes absent breathing (respiratory depression);
- absence of reflexes (comatose state, precoma or conscious coma and in the most serious cases deep coma);
- constriction of the pupil of the eye (miosis).

To treat these symptoms, in addition to naloxone, resuscitation techniques will be necessary, such as cardiac massage, artificial respiration, and the administration of drugs that increase blood pressure (vasopressors).

NALOXONE HYDROCHLORIDE GALENICA SENESE is not effective against respiratory depression caused by

the use of non-opioid drugs.

This medicine should be administered with caution:
- if, in the hours before taking this medicine, you have had serious breathing problems (laryngospasm);
- if you suffer from heart or circulation problems or are taking other medicines that are harmful to the heart.
After the first intervention, the patient must be transferred to the hospital and must be carefully monitored, as the symptoms of poisoning may reappear.

Children and newborns

Naloxone can be used in newborns of mothers who have taken an opioid substance within 4 hours of delivery and in newborns who are not breathing independently, but only as adjunctive therapy.
The use of naloxone is not recommended in newborns of drug-addicted mothers, because it can worsen withdrawal symptoms and seizures.

Other medicines and NALOXONE HYDROCHLORIDE GALENICA SENESE

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.
Take special care and talk to your doctor if you are taking clonidine, a medicine used to treat high blood pressure.

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.
There are no data available to establish the effect of this medicine during pregnancy and breastfeeding.

Driving and using machinery

There are no data available to establish the effect of this medicine on the ability to drive and use machines.

3. How to use NALOXONE HYDROCHLORIDE GALENICA SENESE

Always use this medicine exactly as your doctor, pharmacist, or nurse has told you. If you are not sure, ask your doctor, pharmacist, or nurse.
This medicine will be injected by your doctor or other healthcare professional into a vein (intravenously), under the skin (subcutaneously) or into a muscle (intramuscularly), depending on your needs.
In emergency situations, the intravenous route is recommended, because it produces a more rapid effect.
For intravenous infusion (drip) NALOXONE HYDROCHLORIDE GALENICA SENESE can be diluted in solvents for parenteral use (for example, 0.9% sodium chloride solution or 5% glucose solution). Naloxone should not be mixed with alkaline solutions.
In particular, naloxone should not be administered intravenously together with bisulphites, metabisulfites, high molecular weight anions, or long-chain anions.
Following treatment, the patient must be monitored closely and transferred to the hospital as soon as possible, as symptoms may recur. If necessary, the drug can be administered again.

Use in adults

Treatment of drug overdose (known or suspected)

The recommended starting dose is 0.4 mg/ml (1 vial).
If there is no improvement in breathing after intravenous administration, it is advisable to repeat the dose at intervals of 2 - 3 minutes.

Treatment of postoperative drug-induced depression

The recommended dose is 0.1 to 0.2 mg administered intravenously in increasing doses at intervals of 2 - 3 minutes, until adequate improvement of symptoms is achieved.
Within 1 - 2 hours of the first administration, it may be necessary to repeat the dose, even intramuscularly.
Excessive doses of naloxone can reduce the pain-relieving effect of the analgesic and increase blood pressure.
Too rapid a reversal of the effects of the narcotic medicine may cause nausea, vomiting, sweating or palpitations (tachycardia).

Use in children and adolescents

For the treatment of narcotic overdose (known or suspected), the recommended initial dose is 0.01 mg/ kg body weight, administered intravenously, intramuscularly, or subcutaneously.

The dose can be repeated according to the indications for administration in adults.

If you use more NALOXONE HYDROCHLORIDE GALENICA SENESE than you should

This medicine will be given to you by trained personnel, so an overdose is unlikely to occur.

In case of accidental ingestion/intake of an excessive dose of Naloxone hydrochloride, immediately inform your doctor or go to the nearest hospital.

4. Possible side effects

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

Following the instructions in the package leaflet reduces the risk of side effects. The following side effects may occur:

- nausea;
- tremor;
- sweating;
- increase or decrease in blood pressure;
- convulsions, agitation;
- heart problems (fibrillation, cardiac arrest);
- accumulation of fluid around the lung (pulmonary edema).
- increased growth hormone levels;
- alteration of sensitivity in the limbs (paraesthesia);
- memory disorders;
- respiratory difficulties (dyspnea, hypoxia and respiratory depression, hyperventilation);
- difficulty swallowing (dysphagia);
- hot flashes and redness;
- urge to urinate (micturition);
- vomit;
- acceleration of the heartbeat (ventricular tachycardia);
- hallucinations.

Reporting of side effects

If you experience any side effects, including any not listed in this leaflet, talk to your doctor or pharmacist.

You can also report side effects directly via the national reporting system at http://www.aifa.gov.it/content/segnalazioni-reazioni-avverse .

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store NALOXONE HYDROCHLORIDE GALENICA SENESE

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

Do not use this medicine after the expiry date which is stated on the carton after “EXP.”. The expiry date refers to the last day of that month.

Store this medicine in the original package to protect from light. It is for a single, discontinued use; any remaining dose should not be used.

After first opening the package, the medicine must be used immediately for a single, uninterrupted administration.

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. Package contents and other information

What does NALOXONE HYDROCHLORIDE GALENICA SENESE contain?

NALOXONEGALENICA SENESE HYDROCHLORIDE adults 0.4 mg/ml solution for injection:

- The active substance is naloxone hydrochloride dihydrate. Each 1 ml vial contains 0.4 mg of naloxone hydrochloride dihydrate.
- The other ingredients are water for injections qs, hydrochloric acid.

NALOXONE HYDROCHLORIDE GALENICA SENESE children 0.04 mg/2 ml solution for injection:

- The active substance is naloxone hydrochloride dihydrate. Each 2 ml vial contains 0.04 mg of naloxone hydrochloride dihydrate.
- The other ingredients are water for injections qs, hydrochloric acid.

Description of the appearance of NALOXONE HYDROCHLORIDE GALENICA SENESE and contents of the pack

NALOXONE HYDROCHLORIDE GALENICA SENESE adults 0.4 mg/ml solution for injection

Pack of 10 vials of 1 ml of solution for injection.

NALOXONE HYDROCHLORIDE GALENICA SENESE children 0.04 mg/2 ml solution for injection

Pack of 5 vials of 2 ml of solution for injection.

Marketing Authorisation Holder and Manufacturer Galenica Senese

Pharmaceutical Industry Srl Via Cassia Nord, 351
53014 Monteroni d'Arbia (SI) Italy
This leaflet was last updated on: