

## Package leaflet: Information for the user

### Nyxoid 1.8 mg nasal spray, solution in a single-dose container Naloxone

**Read all of 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. 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

1. What Nyxoid is and what it is used for
2. What you need to know before you receive Nyxoid
3. How Nyxoid is to be given
4. Possible side effects
5. How to store Nyxoid
6. Contents of the pack and other information

#### **1. What Nyxoid is and what it is used for**

This medicine contains the active substance naloxone. Naloxone temporarily reverses the effects of opioids such as heroin, methadone, fentanyl, oxycodone, buprenorphine and morphine.

Nyxoid is a nasal spray used for the emergency treatment of opioid overdose or possible opioid overdose in adults and adolescents over 14 years. Signs of overdose include:

- breathing problems
- severe sleepiness
- not responding to a loud noise or touch.

**If you are at risk of an opioid overdose you should always carry your Nyxoid with you.** Nyxoid works for a short time only to reverse the effects of opioids while you wait for emergency medical attention. It is not a substitute for emergency medical care. Nyxoid is intended for use by appropriately trained individuals.

Always tell your friends and family that you carry Nyxoid with you.

#### **2. What you need to know before you receive Nyxoid**

##### **Do not use Nyxoid**

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

##### **Warnings and precautions**

Nyxoid will be supplied to you only after you or your carer have been taught how to use it.

It is to be given right away and does not take the place of emergency medical care.

- **Emergency services should be called if an opioid overdose is suspected.**

The signs and symptoms of an opioid overdose can return after this nasal spray is given. If this happens, further doses may be given after 2 to 3 minutes using a new nasal spray. The patient should be monitored closely until emergency help has arrived after being given this medicine.

### **Conditions to look out for**

- If you are physically dependent on opioids or if you have received high doses of opioids (for example heroin, methadone, fentanyl, oxycodone, buprenorphine or morphine). You may get strong withdrawal symptoms with this medicine (see later in section 4 of this leaflet under ‘Conditions to look out for’)
- If you take opioids to control pain. The pain may increase when you receive Nyxoid.
- If you use buprenorphine. Nyxoid may not fully reverse breathing problems.

**Tell your doctor** if you have damage to the inside of your nose as this could affect how Nyxoid works.

### **Children and adolescents**

Nyxoid is not for use in children or adolescents under 14 years.

### **Receiving Nyxoid close to giving birth**

**Tell your midwife or doctor** if you have **received Nyxoid** close to or during **labour**.

Your baby could suffer from **sudden opioid withdrawal syndrome**, which could be life-threatening if not treated.

Watch out for the following symptoms in your baby during the first **24 hours** after the baby is born:

- seizures (fits)
- crying more than usual
- increased reflexes.

### **Other medicines and Nyxoid**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

### **Pregnancy, breastfeeding and fertility**

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before receiving a supply of this medicine.

If you are given Nyxoid while you are pregnant or breast-feeding, your baby should be closely monitored.

### **Driving and using machines**

After taking this medicine, you must not drive, operate machinery or engage in any other physically or mentally demanding activity for at least 24 hours, since the effects of opioids may recur.

## **3. How Nyxoid is to be given**

Always use this medicine exactly as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

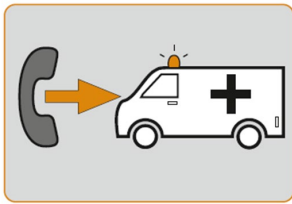
Training will be provided on how to use Nyxoid before it is supplied to you. Below is a step by step guide.

### **Instructions for giving Nyxoid nasal spray:**

1. **Check for symptoms and response.**

- **Check for a response, to see if the person is conscious.** You can shout their name, gently shake their shoulders, talk loudly into their ears, rub their breastbone (sternum), pinch their ear or the bed of their fingernail.
- **Check airways and breathing.** Clear the mouth and nose of any blockages. For 10 seconds check for breathing – is the chest moving? Can you hear breathing sounds? Can you feel breath on the cheek?
- **Check for signs of overdose,** such as: no response to touch or sounds, slow uneven breathing or no breathing, snoring, gasping or gulping, blue or purple fingernails or lips.
- **If an overdose is suspected Nyxoid should be given.**

2. **Call for an ambulance.** Nyxoid is not a substitute for emergency medical care.



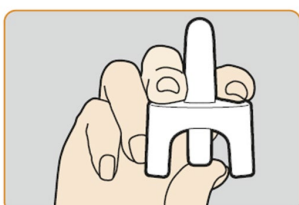
3. **Peel off** the back of the blister from the corner to **remove the nasal spray** from the container. Place the nasal spray within easy reach.



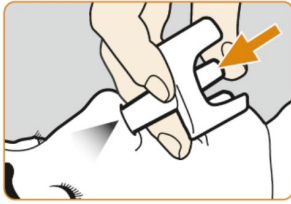
4. Lay the patient on their back. Support the back of the neck and allow the head to tilt back. Clear away anything blocking their nose.



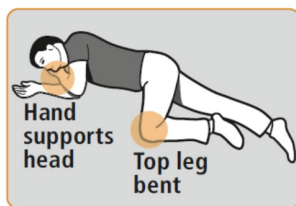
5. Hold the nasal spray with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle. **Do not prime or test the Nyxoid nasal spray before use** as it contains only one dose of naloxone and cannot be reused.



6. Gently insert the device nozzle in **one nostril**. **Press firmly** on the plunger **until it clicks** to give the dose. Remove the nasal spray nozzle from the nostril after giving the dose.



7. Place the patient into the **recovery position** on their side with mouth open pointing towards the ground and stay with the patient until the emergency services arrive. Watch for an improvement in the patient's breathing level, alertness and response to noise and touch.



8. If the patient is **no better** within **2-3 minutes**, a **second dose can be given**. Be aware – even if they wake up, they may become unconscious again, and stop breathing. If this happens, a second dose can be given immediately. Give Nyxoid in the other nostril using a new Nyxoid nasal spray. This can be done **while the patient is in the recovery position**.
9. If the patient does not respond to two doses, further doses may be given (if available). Stay with the patient and continue to watch for an improvement until the emergency services arrive who will give further treatment.

In patients who are unconscious and not breathing normally additional life-saving support should be given if possible.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects although not everyone gets them. The side effects below may happen with this medicine.

##### Conditions to look out for

Nyxoid can cause **acute withdrawal symptoms** if the patient is dependent on opioid drugs.

Symptoms can include:

- Fast heart rate, high blood pressure
- Body aches and stomach cramps
- Feeling sick, vomiting, diarrhoea
- Sweating, fever, goose bumps, shivering or trembling
- Changes in behaviour including violent behaviour, nervousness, anxiety, excitement, restlessness or irritability

- Unpleasant or uncomfortable mood
- Increased skin sensitivity
- Difficulty in sleeping.

Acute withdrawal symptoms occur uncommonly (may affect up to 1 in 100 people).

**Tell your doctor** if you experience any of these symptoms.

Very common: may affect more than 1 in 10 people

- Feeling sick

Common: may affect up to 1 in 10 people

- Dizziness, headache
- Fast heart rate
- High blood pressure, low blood pressure
- Being sick (vomiting)

Uncommon: may affect up to 1 in 100 people

- Tremor
- Slow heart rate
- Sweating
- Irregular heart beat
- Diarrhoea
- Dry mouth
- Rapid breathing

Very rare: may affect up to 1 in 10,000 people

- Allergic reactions such as swelling of the face, mouth, lips or throat, allergic shock
- Life-threatening irregular heartbeat, heart attack
- Build-up of fluid in the lungs
- Skin problems such as itching, rash, redness, swelling, severe flaking or peeling of the skin.

## **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 via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Nyxoid**

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, blister pack and the label after EXP. The expiry date refers to the last day of that month.

Do not freeze.

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

## **6. Contents of the pack and other information**

### **What Nyxoid contains**

- The active substance is naloxone. Each nasal spray contains 1.8 mg of naloxone (as hydrochloride dihydrate).
- The other ingredients are trisodium citrate dihydrate, sodium chloride, hydrochloric acid, sodium hydroxide and purified water.

### **What Nyxoid looks like and contents of the pack**

This medicine contains naloxone in 0.1 ml of a clear, colourless to pale yellow solution in a pre-filled nasal spray, solution in a single dose container.

Nyxoid is packed in a carton containing 2 nasal sprays individually sealed in blisters. Each nasal spray contains one single dose of naloxone.

### **Marketing Authorisation Holder:**

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### **Manufacturers:**

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