

## VasoKINOX®

450ppm

(nitric oxide for inhalation), medicinal gas compressed

### Consumer Medicine Information

#### What is in this leaflet?

This leaflet answers some common questions about VasoKINOX. It does not contain all the available information. It does not take the place of talking to your specialist, doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed up the risks of using VasoKINOX against the benefits it is expected to have for you or your child.

**If you have any questions about using this medicine, ask your doctor or pharmacist.**

**Keep this leaflet.**

You may need to read it again.

#### What dosage form does VasoKINOX come in?

VasoKINOX is a medicinal product that is in the form of a gas and is packaged in gas cylinders in a concentration of 450 parts per million (ppm).

#### What does VasoKINOX contain?

The active substance is nitric oxide, its dosage is 450 ppm mole/mole. The other ingredient is nitrogen. Nitrogen is a major component of the air we breathe.

#### What is VasoKINOX used for?

VasoKINOX is a gas mixture, composed of nitric oxide and nitrogen, used to treat acute pulmonary hypertension (increase in blood pressure in the pulmonary circulation), which can occur during heart surgery.

VasoKINOX is a 'PRESCRIPTION ONLY MEDICINE'. It is to be given only to the person for whom it has been prescribed.

#### How VasoKINOX works?

VasoKINOX can improve the flow of blood through the lungs by relaxing the cells in the blood vessels and allowing the blood vessels to widen. This may help to decrease the blood pressure and increase the amount of oxygen that reaches the blood.

#### When VasoKINOX should not be used

**Do not use VasoKINOX if:**

- you are allergic to nitric oxide or nitrogen
- in newborns who have the following heart defects:
  - right-to-left shunt
  - malignant left-right arterial canal

**VasoKINOX should not be used in premature infants born before 34 weeks from conception.**

Tell your doctor if you are pregnant or breast feeding. VasoKINOX should not be used during pregnancy. The effect of VasoKINOX in pregnant woman is unknown.

It is not known if VasoKINOX is excreted in breast milk. Talk to your doctor, who will help you to decide if breast feeding should be stopped or VasoKINOX should be stopped.

#### How to use VasoKINOX

VasoKINOX is a medical gas only administered in hospitals by healthcare professionals.

**Your doctor will determine the appropriate dose of VasoKINOX** as well as the length of treatment, depending on your condition and age.

VasoKINOX is administered **by inhalation, by mechanical ventilation** after dilution in an air/oxygen mixture for patients in Intensive Care Units under respiratory assistance and also in the operating room.

On contact with oxygen, nitric oxide can be converted into nitrogen dioxide, which is an irritant for the bronchial tubes. This is why, throughout administration, the concentrations of inhaled nitric oxide and nitrogen dioxide are continuously measured. In certain clinical circumstances, administration of nitric oxide by ventilation through a mask is possible for a very short duration (5 to 10 mn).

**VasoKINOX treatment should not be stopped abruptly.**

**If you take too much (overdose)**

As VasoKINOX will be given under the supervision of your doctor it is unlikely that you will receive too much.

Your doctor will take the appropriate measures if too much VasoKINOX is received.

**Discontinuation of VasoKINOX treatment:**

At the end of the treatment in intensive care, the doctor will gradually reduce the dose of VasoKINOX administered (withdrawal stage), by monitoring the change in your condition.

In fact, a sudden halt in the treatment after several hours of administration may result in the deterioration of your clinical status: this is called the "rebound effect".

If you have other questions on the use of this medicine, ask your doctor for more information.

#### Before you are given VasoKINOX

Other things to be aware of before being treated with VasoKINOX include:

**Patients with abnormal heart function:**

In patients whose hearts are less efficient than normal at pumping blood around the body, nitric oxide can increase the chance of serious side effects occurring, such as the build up of fluid in the lungs, worsening of abnormal heart function, low blood pressure, abnormally slow heart beat, and stopping of the heart.

**Using other medicines:**

Tell your doctor if you are taking, have recently taken any other medicines.

The doctor will decide whether it is necessary to treat you with VasoKINOX and with other medicines at the same time.

VasoKINOX must be administered with caution if the following medicines are taken at the same time:

- Medicines called 'nitric oxide donors' – such as drugs containing sodium nitroprusside and nitroglycerine. Their

effect can add to the effect of VasoKINOX

- Methaemoglobin-generating drugs – such as drugs containing alkylated nitrates and sulphamides, prilocaine. These can increase the blood concentration of methaemoglobin
- Medicines which widen your blood vessels such as prostacyclin and its analogues

#### Side effects

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

Side effects that are very commonly seen (affects more than 1 user in 10) in association with VasoKINOX therapy include:

- Low level of blood platelets.

Side effects that are commonly seen (affects more than 1 user in 100) in association with VasoKINOX therapy include:

- Low blood pressure, airless or collapsed lung.

Side effects that may be seen, but uncommonly (affects between 1 user in 100 and 1 user in 1000) are:

- Increased amount of methaemoglobin (a form of haemoglobin unable to carry oxygen) that reduces the release of oxygen to body tissues.

These side effects may happen when VasoKINOX is stopped suddenly:

- Bradycardia (low heart beat)
- Hypoxemia (too low amount of oxygen in the blood)

These side effects may happen if you are accidentally exposed to VasoKINOX:

- Headache,
- dizziness,
- dry throat
- shortness of breath

You should directly inform the personnel if you experience headache while being in close proximity to your child or a patient receiving VasoKINOX.

If any of the side effects becomes serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

Other side effects not listed above occur in some people.

#### After using VasoKINOX

##### Storage and Transport

- The storage of VasoKINOX cylinders is undertaken in hospital.
- Keep this medicine out of the sight and reach of children.
- The cylinder must be protected to avoid breakage or falling and must be kept away from any inflammable or combustible materials and from humidity.
- This medicinal product does not require any special temperature storage conditions.

- The cylinders must be firmly secured to hold them in a vertical position and must be stored in a well-ventilated area.
- Do not use this medicine after the expiry date which is stated on the batch label.

### ***Disposal***

When the cylinder is empty, do not dispose of it. Empty cylinders will be collected by the supplier.

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### **Product description**

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VasoKINOX is supplied in aluminium alloy gas cylinders with a nitric oxide concentration of 450ppm mol/mol (Nitric Oxide (NO) 0.450 ml in Nitrogen (N<sub>2</sub>) 999.55 ml).

VasoKINOX® is available in the following sizes:

5 L: aluminium alloy cylinder (white painted body, turkish blue painted shoulder), equipped with a stainless steel residual pressure valve with a specific outlet connector.

11L: aluminium alloy cylinder (white painted body, turkish blue painted shoulder), equipped with a stainless steel residual pressure valve with a specific outlet connector.

20 L: aluminium alloy cylinder (white painted body, turkish blue painted shoulder), equipped with a stainless steel residual pressure valve with a specific outlet connector.

### ***Name and address of sponsor:***

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