

Package leaflet: Information for the patient

Sedaconda 100% v/v inhalation vapour, liquid

isoflurane

Read all of this leaflet carefully before you start receiving 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.
- 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 Sedaconda is and what it is used for
2. What you need to know before you receive Sedaconda
3. How you receive Sedaconda
4. Possible side effects
5. How to store Sedaconda
6. Contents of the pack and other information

1. What Sedaconda is and what it is used for

Sedaconda contains an active substance called isoflurane which belongs to a medicine group called anaesthetics. It is used to provide sedation (a state of calm, drowsiness or sleep) for adult patients who are in need of mechanical ventilation (a treatment with a special machine that helps patients to breathe) during intensive care.

2. What you need to know before you receive Sedaconda

You will not be given Sedaconda

- If you are allergic to isoflurane or other halogenated anaesthetics.
- If you, or anyone in your family, have ever experienced a rapid rise in body temperature during sedation or anaesthesia (a rare condition known as malignant hyperthermia). For more information see section “Possible side effects”.

Warnings and precautions

Talk to your doctor or nurse before receiving Sedaconda if:

- You have ever had QT prolongation (abnormal reading on an electrocardiogram) or torsade de pointes (life-threatening irregular heartbeat). Isoflurane has sometimes been known to cause these.
- You have a mitochondrial disease. Mitochondrial diseases are a group of rare genetic conditions that occur when mitochondria (small structures in the cells) fail to produce enough energy for the body to function properly.
- You have a heart disease (e.g., coronary heart disease).
- You have previously been given an inhaled anaesthetic, particularly within the last 3 months. You may be at increased risk of liver injury.
- You have raised intracranial pressure (pressure around your brain) due to head injury, brain tumour or another condition. Sedaconda may further raise the pressure inside your skull.
- You have low blood pressure, low blood volume or are debilitated. You may need a lower dose of Sedaconda.
- You have a liver disorder.
- You have a condition that affects the nerves and muscles (a neuromuscular disease, e.g., Duchenne muscular dystrophy or myasthenia gravis).
- You are taking medicines called muscle relaxants (see section “Other medicines and Sedaconda”).

Sedaconda can cause malignant hyperthermia, which is a rapid and significant rise in body temperature accompanied by muscle stiffness and other symptoms (see section 4).

Sedaconda may cause hyperkalemia (increases in serum potassium levels) in rare cases (see section 4). Patients with neuromuscular disease appear to be most vulnerable.

Sedaconda may cause difficulties in breathing (respiratory depression) (see section 4).

Children and adolescents

This medicine should not be given to children and adolescents under 18 years of age, as there is limited experience with this medicine in this age group.

Other medicines and Sedaconda

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

This is particularly important if you are taking any of the following medicines:

- Certain medicines for depression, called non-selective monoamine oxidase [MAO]-inhibitors, such as isocarboxazid, nialamide, phenelzine, etc. Your doctor will not give you Sedaconda for at least 15 days after MAO-inhibitor intake.
- Medicines called beta-sympathomimetics (a broad group of medicines affecting the part of your nervous system that work automatically), e.g., isoprenaline, adrenaline, noradrenaline. Taking these medicines with Sedaconda may cause your heartbeat to become irregular.
- Medicines called indirect-acting sympathomimetics such as amphetamines and their derivatives, psychostimulants, appetite suppressants, ephedrine and its derivatives. Taking these medicines with Sedaconda may cause high blood pressure.
- Beta blockers (a group of medicines used to treat high blood pressure and certain heart diseases). Taking these medicines with Sedaconda may impair so-called heart compensation reactions (reactions that help your body to make up for reduced blood and oxygen supply caused by heart insufficiency).
- Isoniazide (an antibiotic used to treat tuberculosis), which can increase the risk of liver damage.
- Calcium channel blockers (used to treat high blood pressure and certain heart diseases) such as amlodipine, diltiazem, nifedipine, verapamil.
- Opioids (e.g., morphine, fentanyl), benzodiazepines (e.g., midazolam, diazepam) and other sedative medicines, which may cause slow and ineffective breathing.
- Medicines used to relax the muscles (e.g., suxamethonium, pancuronium, atracurium, vecuronium). Sedaconda may increase their effects.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before getting this medicine. Sedaconda may cause increased blood loss, for example if you need an operation of the womb, or are giving birth. Your doctor will not give you this medicine unless the potential benefit outweighs the potential risks to you and your baby.

If you have been breast-feeding before being given Sedaconda, you should stop breast-feeding until the medicine is cleared from your body. Your doctor will let you know when it is safe for you to continue breast-feeding.

Driving and using machines

Sedaconda may impair your ability to drive and use machines for up to 6 days.

You should not drive or use machines until your doctor advises that it is safe to do so.

3. How to use Sedaconda

Sedaconda will only be given to you by qualified and experienced medical staff. The doctor will decide on the appropriate dose for you depending on your age, health condition, and the level of sedation (sleepiness) that you need.

The doctor will give you the correct starting dose to achieve the required level of sedation by carefully watching your responses and vital signs (such as pulse, blood pressure and breathing etc.).

Sedaconda is a liquid that is changed to vapour (gas) with the use of a vapouriser. It is for inhalation use, which means you will breathe it in as a vapour.

If you receive more Sedaconda than you should

If you are given too much Sedaconda and are in deep sedation, your blood pressure may go down (hypotension) and your breathing may be slow and ineffective. Your doctor will take supportive measures to correct blood pressure and breathing.

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

4. Possible side effects

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

Side effects where the frequency is not known (cannot be estimated from available data):

- anaphylactic reaction (a severe, potentially life-threatening allergic reaction), other allergic reactions (manifesting as red, itchy, blistered, dry or cracked skin, rash, shortness of breath, wheezing, discomfort in the chest, swelling of the face),
- elevated sugar or potassium levels in the blood,
- mood changes,
- mental impairment and convulsion, which is a medical condition when body muscles contract and relax rapidly and repeatedly, resulting in uncontrolled actions of the body,
- irregular heartbeat, slow heartbeat, cardiac arrest (a condition in which the heart suddenly stops beating), QT prolongation (abnormal reading on the electrocardiogram) and torsade de pointes (life-threatening irregular heartbeat),
- bronchospasm (tightening of the airway muscles resulting in breathing problems), shortness of breath, wheezing, slow shallow breathing, laryngospasm (tightening of the vocal cords that temporarily makes it difficult to speak or breathe),
- blockage in the intestines, vomiting, nausea,
- liver cells death (hepatic necrosis) or damage, elevated levels of bilirubin (red blood cells breakdown product) in the blood,
- blood test results showing a change in kidney function: elevated levels of creatinine and decreased levels of urea,
- rapid and significant rise in body temperature (malignant hyperthermia). It is a serious condition that will be immediately treated by your doctor.
- discomfort in the chest, chills,
- changes in blood tests results: abnormal levels of certain liver enzymes, increased number of white blood cells, increased levels of fluoride and decreased cholesterol levels,
- abnormal results in electroencephalogram (a test that evaluates the electrical activity in the brain),
- presence of myoglobin (a muscle protein) in the urine, rhabdomyolysis (severe muscle damage).

Side effects reported as common (may affect up to 1 in 10 people) in a clinical trial:

- rapid heartbeat
- agitation, delirium (sudden change in mental state, which may be confusion, agitation, personality change, and difficulties with understanding and memory) during or after sedation
- low blood pressure

- increased blood levels of creatine phosphokinase (a substance from the muscles)
- feeling of sickness, vomiting

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 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 Sedaconda

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

The shelf life of Sedaconda after attaching the Sedaconda Filling Adapter is 14 days.

Do not store above 30°C. Keep the bottle in the outer carton in order to protect from light.

Any unused medicine or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What Sedaconda contains

The active substance is isoflurane 100% v/v. There are no other ingredients.

What Sedaconda looks like and contents of the pack

Sedaconda is an inhalation vapour, liquid. It is a clear, colourless liquid available in 100 ml and 250 ml amber coloured glass bottles.

Pack sizes:

6 x 100 ml

6 x 250 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Sedana Medical AB

Vendevägen 89

182 32 Danderyd

Sweden

Manufacturer

Piramal Critical Care B.V.

Rouboslaan 32 (ground floor)

2252 TR, Voorschoten

The Netherlands

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

Austria: Sedaconda 100 % V/V Flüssigkeit zur Herstellung eines Dampfes zur Inhalation

Belgium: Sedaconda 100 % V/V liquide pour inhalation par vapeur; Sedaconda 100% V/V vloeistof voor inhalatiedamp; Sedaconda 100 % V/V Flüssigkeit zur Herstellung eines Dampfes zur Inhalation

Croatia: Sedaconda 100% V/V para inhalata, tekućina

Denmark: Sedaconda

Finland: Sedaconda 100 % V/V inhalaatiohöyry, neste

France: Cedaconda 100 % V/V liquide pour inhalation par vapeur
Germany: Sedaconda 100 % V/V Flüssigkeit zur Herstellung eines Dampfes zur Inhalation
Ireland: Sedaconda 100% v/v inhalation vapour, liquid
Netherlands: Sedaconda 100% V/V vloeistof voor inhalatiedamp
Norway: Sedaconda
Poland: Sedaconda 100 % V/V płyn do sporządzenia inhalacji parowej
Portugal: Sedaconda 100% V/V líquido para inalação por vaporização
Slovenia: Sedaconda 100 % V/V para za inhaliranje, tekočina
Spain: Sedaconda 100% V/V líquido para inhalación del vapor
Sweden: Sedaconda 100 % V/V inhalationsånga, vätska

This leaflet was last revised in MM/YYYY.

The following information is intended for healthcare professionals only:

Sedaconda 100% v/v inhalation vapour, liquid

Administration

Sedaconda should only be administered and inhaled via the delivery device Sedaconda ACD (Anaesthetic Conserving Device), utilising the Sedaconda Filling Adapter and should only be used with intubated or tracheotomized patients with a protected airway. Sedaconda should only be administered by medical staff familiar with the management of mechanically ventilated patients, the Sedaconda ACD and the pharmacodynamics of isoflurane.

Isoflurane should only be administered in an adequately equipped environment by personnel who are trained in handling volatile anaesthetic agents.

The Sedaconda ACD is a modified passive Heat and Moisture Exchanger (HME) and as such adds dead space to the breathing circuit. The patient's ventilatory status should be taken into consideration when selecting the Sedaconda ACD size, see the Instructions for Use delivered together with the Sedaconda ACD.

Full information on how to use the Sedaconda ACD and Sedaconda Filling Adapter are presented in the Instructions for Use document supplied with the devices.

Please read the Summary of Product Characteristics for Sedaconda and the Instructions for Use delivered together with the Sedaconda ACD and Sedaconda Filling Adapter before the set-up of the Sedaconda ACD administration system and initiating sedation.