

## Package leaflet: Information for the patient

# Sedaconda 100% inhalation vapour, liquid

isoflurane 100%

**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 adults and children, 3 years and older, who are in need of mechanical ventilation (a treatment with a special machine that helps patients to breathe).

Sedaconda is a clear colourless liquid and is changed to vapour (gas) with the use of a vapouriser (a special anaesthetic device). You will inhale Sedaconda in as a vapour.

### 2. What you need to know before you receive Sedaconda

#### You will not be given Sedaconda

- If you are allergic to isoflurane or other similar 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 under 3 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 a qualified and experienced doctor in the hospital. 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

Side effects reported as very common in children (may affect more than 1 in 10 people) in a clinical trial:

- low blood pressure

#### 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 Yellow Card Scheme Website: [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 Sedaconda

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the label after EXP.

The expiry date refers to the last day of that month.

Once opened, the contents of the bottle should be used within 14 days.

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

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

##### What Sedaconda contains

The active substance is isoflurane. There are no other ingredients.

##### What Sedaconda looks like and contents of the pack

Sedaconda is an inhalation vapour, liquid. It is a 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  
Svärdvägen 3A  
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#### Manufacturer

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**This leaflet was last revised in 04/2025.**

#### The following information is intended for healthcare professionals only:

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##### Administration

Sedaconda should only be administered and inhaled via the Sedaconda ACD delivery system, 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.

The Sedaconda ACD is a modified passive heat-moisture exchanger 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 (IFU) delivered together with the Sedaconda ACD.

Full information on how to use the Sedaconda ACD and Sedaconda filling adapter are presented in the IFU document supplied with the devices.

Please read the Summary of Product Characteristics for Sedaconda and the IFU delivered together with the Sedaconda ACD and Sedaconda filling adapter before the set-up of the Sedaconda ACD administration system and initiating sedation.

##### Scavenging

Precautions should be taken to avoid spillage and room pollution during Sedaconda treatment. Such precautions include adequate general ventilation in the intensive care room, the use of a well-designed scavenging system, work practices to minimize leaks and spills while Sedaconda is in use, and routine equipment maintenance to minimize leaks. Such precautions have been shown to be effective in keeping occupational exposure at a low level.