

Package leaflet: Information for the patient

AErrane (isoflurane), 100% v/v inhalation vapour, liquid

Active substance: isoflurane

Read all of this leaflet carefully before you are given this medicine. 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, nurse or pharmacist.
- If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet

In this leaflet:

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

1. What AErrane is and what it is used for

AErrane contains isoflurane. AErrane is a general anaesthetic used in surgery. It is an inhalation anaesthetic (it is given to you as a vapour for you to breathe in). Breathing in isoflurane vapour causes you to fall into a deep, painless sleep. It also maintains a deep, painless sleep (general anaesthesia) during which you can undergo surgery.

2. What you need to know before you are given AErrane

Your doctor will not give you AErrane if:

- you are allergic (hypersensitive) to isoflurane or other inhalation anaesthetics such as desflurane, sevoflurane, halothane and enflurane
- you, or any relative suffer from a condition called malignant hyperthermia. Malignant hyperthermia is when you suddenly develop a dangerously high body temperature during or shortly after surgery.
- following anaesthesia with AErrane or other inhalation anaesthetics (e.g. desflurane, sevoflurane, halothane) in the past, you have had:
 - liver problems
 - jaundice (yellowing of the skin and white of the eyeballs)
 - unexplained fever
 - increased levels of white blood cells called leucocytes (leucocytosis)
 - increased levels of a certain type of white blood cells called eosinophils (eosinophilia)

You must not be given AErrane for operations during pregnancy, childbirth or the period just after childbirth. AErrane may, however, be used for a Caesarean section.

AErrane will not be used for dental procedures outside of hospital or daycare units.

If any of the above applies to you, please inform your doctor, surgeon or anaesthetist before you are treated with this medicine.

Warnings and Precautions

Talk to your doctor, nurse or pharmacist before being given AErrane.

Your doctor will take special care with this medicine if:

- You have a disorder of the cells (a condition called mitochondrial disorder)
- you suffer from liver problems such as:
 - hepatitis (inflamed liver)
 - cirrhosis of the liver (replacement of healthy liver tissue with scar tissue). This can happen if you drink too much alcohol
 - any other liver disease
- you have recently had an operation for which you received general anaesthesia with an inhalation anaesthetic
- You are suffering from the symptoms of any illness other than those connected with your operation, such as severe headaches, nausea, vomiting, severe chest pain or a condition that affects muscles (a neuromuscular disease e.g. Duchenne muscular dystrophy or myasthenia gravis).
- You suffer with bronchoconstriction (a tightening of the lungs and airways leading to coughing, wheezing or shortness of breath).
- The patient is a child under two years of age.

Your doctor may give you less AErrane if:

- you have a low blood volume (hypovolaemia)
- you have low blood pressure (hypotension)
- you are weakened (debilitated)

AErrane can cause irritation of the lining of the mouth and the airways, which may result in an increased saliva flow and increased secretions from the windpipe and upper airways. In children this may make it harder for them to breathe in or can cause a muscle spasm of the vocal chords (voicebox) called a laryngospasm.

If you are given AErrane, you may have brief:

- changes in liver function
- increases in blood sugar (glucose) levels
- decreases in blood levels of a fat called cholesterol
- changes in blood enzyme levels

AErrane can cause malignant hyperthermia (when you suddenly develop a dangerously high body temperature during or shortly after surgery). Fatal outcome of malignant hyperthermia has been reported with AErrane.

Your doctor will monitor your breathing during treatment, especially if you are given any other medicines which can affect your breathing, like:

- sedatives (e.g. diazepam, nitrazepam)
- strong pain killers (e.g. opioids such as fentanyl, morphine and remifentanyl)

If any of the above apply to you or your child, check with your doctor, nurse or pharmacist. You may need to be checked carefully and your treatment may be changed.

Other medicines and AErrane:

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you have obtained yourself, without a prescription, including herbal medicines and natural products.

You must take special care if you are also taking any of the following medicines:

- non selective MAOIs (monoamine oxidase inhibitor such as phenelzine, isocarboxazid): Your doctor will instruct you to stop taking such medicines 15 days before you have your operation.
- heart medicines called beta-sympathomimetics (e.g. isoprenaline) and alpha- and beta-sympathomimetics (e.g. adrenaline, noradrenaline): These may increase your heart rate and cause a serious irregular heartbeat.
- beta-blockers (e.g. atenolol, metoprolol): These are heart medicines often given to treat a high blood pressure.
- isoniazid: A medicine used to treat tuberculosis (TB). Your doctor will instruct you to stop using isoniazid one week before your operation. Do not start taking isoniazid again until 15 days after your operation.
- indirect sympathomimetic drugs e.g.:
 - amphetamines, amphetamine derivatives (used to treat attention-deficit hyperactivity disorder (ADHD))
 - drugs which reduce your appetite
 - ephedrine and ephedrine derivatives (commonly found in cough and cold medicines)

These medicines may cause an increased risk of high blood pressure when given together with AErrane. Your doctor will instruct you if and when to stop these medicines.

- muscle relaxants (e.g. suxamethonium, pancuronium, atracurium, vecuronium). These medicines are used during general anaesthesia to relax your muscles. Your anaesthetist may need to reduce the dose of these medicines.
- opioids (e.g. morphine, fentanyl, remifentanyl): These medicines are strong pain killers and are often used during general anaesthesia.
- calcium antagonists: Used for treating high blood pressure (e.g. felodipine, nicardipine)

If you are not sure if any of the above applies to you, talk to your doctor, nurse or pharmacist before having AErrane.

Using AErrane with food and drink

AErrane is a medicine to make and keep you asleep so you can undergo surgery. You should ask your doctor, surgeon or anaesthetist when and what you can eat or drink after you wake up. You should not drink alcohol. Your doctor will tell you when you can resume drinking alcohol.

Pregnancy and breast-feeding

You will only be given AErrane whilst you are pregnant if the benefit outweighs the risk, as there is limited data of use in pregnant women. However, lower doses of AErrane can be used during Caesarian section.

As it is not known if AErrane is excreted in human milk, you should avoid breast feeding after an operation if you were given AErrane as the general anaesthetic.

Consult your doctor, surgeon or anaesthetist if you are pregnant, might be pregnant, or if you are breast-feeding.

Driving and using machines

Do not drive or operate tools or machines for at least 24 hours after your operation if you were given AErrane. Receiving an anaesthetic may influence your alertness and behaviour which may affect your ability to carry out normal tasks for up to 6 days. Make sure that someone takes you home after your operation.

3. How you will be given AErrane

The recommended dose

AErrane will ALWAYS be administered to you by an anaesthetist. They will decide on the dose you will receive, depending on your age, weight and the type of operation you are having.

Your child should be monitored closely during the administration of Isoflurane

Inducing sleep at the start of anaesthesia

Isoflurane is not recommended in infants and children for inducing sleep at the start of anaesthesia.

Medication before anaesthesia

The Anaesthetist may decide to give your child medication to counter act the possible reduction in breathing and heart rate effects which may occur with the use of Isoflurane.

AErrane is produced from liquid isoflurane in a vaporiser. You may receive AErrane in one of two ways:

- you may be given an injection of another anaesthetic to make you sleep before being given AErrane through a mask. This is the most common way that you may receive AErrane.

or

- you may be asked to breathe the isoflurane vapour through a mask to make you sleep. You will fall asleep quickly and very easily. This is a less common way to receive AErrane.

After your surgery, your anaesthetist will stop giving you AErrane. You will then wake up in a few minutes.

If you have too much AErrane If you are given too much AErrane the medicine will be stopped. You will be given pure oxygen. Your blood pressure and heart function will be carefully checked while you recover.

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

4. Possible Side Effects

Like all medicines, this medicine can cause side effects.

Most side effects are mild to moderate in their severity and are brief but there may be some serious side effects.

Tell your doctor, nurse or pharmacist straight away if you notice any of the following side effects, which can be serious.

Common (may affect up to 1 in 10 people)

A tightening of your lungs and airways causing a difficulty in breathing

Irregular heart beat or palpitations

Low blood pressure

Slow shallow breathing

Cough

Shivering, chills

Increases in blood sugar or potassium levels

Abnormal levels of certain cells or products found in your blood

Uncommon (may affect up to 1 in 100 people)

Nausea and vomiting

Rare (may affect up to 1 in 1,000 people)

Abnormal heartbeat (arrhythmias) and death associated with the use of inhaled anaesthetics in children shortly after surgery

Raised body temperature due to malignant hyperthermia

Inability of the liver to function properly, including liver injury, hepatitis, jaundice, liver cell death

Muscles of your intestine may stop working temporarily, causing discomfort, bloating and vomiting

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

Presence of carboxyhaemoglobin in the blood

Not known (the number of people affected is unknown)

Allergic reaction, hypersensitivity

Haemorrhage (uncontrolled bleeding)

Agitation, alterations in mood, sometimes extreme

Convulsions, confusion, mental impairment

Shortness of breath, wheezing, chest discomfort

Skin rash, swelling of the face

Increases in blood fluoride levels (due to your body breaking down isoflurane)

Abnormal results from a EEG (electroencephalogram) test

Abnormal electrocardiogram (ECG), change in heart rate or rhythm (eg slow heart beat or fast heart beat)

Cardiac arrest

Presence of myoglobin (material from the muscles) in the urine
Muscle destruction
Increased blood levels of an enzyme called Creatinine Phosphokinase.

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971 Fax: +353 1 6762517 Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5. How to store AErrane

Keep this medicine out of the sight and reach of children

This medicine requires no special storage conditions.

Do not use AErrane after the expiry date that is printed on the label. The expiry date refers to the last day of that month.

Do not throw 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. Contents of the pack and other information

What AErrane contains

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

What AErrane looks like and contents of the pack

AErrane is a liquid.
It is supplied in 100 ml and 250 ml bottles with screw cap closures.

Not all pack sizes may be marketed.

The Marketing Authorisation holder is Baxter Healthcare Limited
Caxton Way, Thetford
Norfolk IP24 3SE, UK

AErrane is manufactured by
Baxter S.A.
Lessines, Belgium

Baxter Manufacturing Sp. z o.o.
Lublin, Poland

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

This leaflet was last revised in October 2015

For information about AErrane or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder:
Tel: +44 1635 206 345

Baxter and AErrane are trademarks of Baxter International Inc.