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Baxter

Package leaflet: Information for the patient

AErrane (isoflurane) Liquid for Inhalation

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. What will happen after receiving AErrane?
5. How AErrane is stored
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 unexplained liver problems with:
 - jaundice (yellowing of the skin and white of the eyeballs)
 - 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.

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 slime production 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 having an abortion you may suffer increased loss of blood if you are given AErrane.

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)

Children Rarely, inhaled anaesthetics can cause problems with heart rhythm in children. This can result in death in the period immediately after the operation. These problems are seen in children that suffer from a disease of the nerves and muscles (neuromuscular disease), particularly a disease called 'Duchenne muscular dystrophy'. In most, but not all of these cases a muscle relaxant named succinylcholine was given at the same time.

If children are given AErrane to bring on (induce) anaesthesia this can cause unwanted side effects such as:

- increased saliva flow
- increased secretions in the windpipe and upper airways

These can cause a muscle spasm of the vocal chords (voicebox) called a laryngospasm.

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 – these medicines are used to treat depression): 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). 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)

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 Caesarean 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

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 counteract 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.

4. What will happen after receiving AErrane?

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are mild to moderate in their severity and are brief but there may be some serious side effects.

If you or your child suffer from any unusual or unexpected symptoms after an operation tell your doctor or anaesthetist IMMEDIATELY.

The most commonly reported side effects are:

- A tightening of your lungs and airways causing a difficulty in breathing
- Increases in blood sugar levels or potassium levels. There have been rare reports of abnormal heartbeat (arrhythmias) and death associated with the use of inhaled anaesthetics in children shortly after surgery

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

Not known (the number of people affected is unknown)

- Presence of carboxyhaemoglobin in the blood
- Allergic reaction
- Hypersensitivity
- Agitation, alterations in mood, sometimes extreme
- Confusion, convulsions, mental impairment
- Irregular heart beat or palpitations
- Abnormal electrocardiogram (ECG), change in heart rate or rhythm
- Cardiac arrest
- Low blood pressure
- Haemorrhage (uncontrolled bleeding)
- Slow shallow breathing
- Shortness of breath, wheezing
- A muscle spasm of the vocal chords (voice box) called a laryngospasm
- Swelling of the face
- Contact dermatitis
- Skin rash
- Increased blood levels of an enzyme called creatinine
- Decreased blood levels of a substance called urea
- Muscles of your intestine may stop working temporarily, causing discomfort, bloating and vomiting
- Nausea and vomiting
- Inability of the liver to function properly, including liver injury, liver cell death
- Increased blood levels of a substance called bilirubin
- Shivering, chills
- Raised body temperature due to malignant hyperthermia
- Chest discomfort
- Abnormal levels of certain cells or products found in your blood
- Increases in blood fluoride levels (due to your body breaking down isoflurane) Abnormal results from a EEG (electroencephalogram) test
- Presence of myoglobin (material from the muscles) in the urine
- Muscle destruction

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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: www.mhra.gov.uk/yellowcard

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

5. How AErrane is stored

Keep out of 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.

MARKETING AUTHORISATION HOLDER

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

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For information about AErrane or to request this leaflet in formats such as audio or large print please contact the Marketing Authorisation Holder: Tel: 01635 206345

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