Package leaflet: Information for the patient
HALOTHANE 100% INHALATION VAPOUR, LIQUID

Read all of this leaflet carefully before you start taking 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 or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Halothane is and what it is used for
   Halothane is an inhaled, general anaesthetic. It acts on the brain and causes unconsciousness. Halothane is used to put you to sleep and maintain your level of unconsciousness during an operation. It stops you knowing what is going on during surgical operations and other procedure. Normally you will receive another medicine to sedate you and to dry your mouth. You will be given halothane as a gas in the air you breathe to keep you asleep during the operation.

2. What you need to know before you take Halothane

   Do not take Halothane
   - If you are hypersensitive to halothane or to other similar anaesthetics.
   - If you are under 18 years of age and are having dental treatment outside hospital.
   - If you or any member of your family suffered from a condition known as malignant hyperpyrexia (a sudden severe fever), when having an anaesthetic during a previous operation.
   - If you have reacted badly to halothane or other similar anaesthetic following a previous operation e.g. you developed jaundice (yellowing of the skin and eyes), fever, liver or blood problems.

   Exposure to halothane within three months is to be avoided unless there are overriding reasons for its re-use

Warnings and precautions

Talk to your doctor before taking Halothane

- If you have ever been given halothane before.
- If you have had an allergic reaction to a medicine or food.
- If you have suffered a head injury in the last few days.
- If you are, or think you might be, pregnant.
- If you are breastfeeding.
- If you have a disease of your liver or kidneys.
- If you suffer from phaeochromocytoma (high blood pressure due to a tumour near the kidneys).
- If you suffer from myasthenia gravis (Chronic fatigue and muscle weakness, especially in the face and throat).
- If you suffer from porphyria.
Other medicines and Halothane
Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines:
- Any Medicines used to treat high blood Pressure (Hypertension)
- Medicines such as methylphenidate, used to treat ADHD
- Medicines such as levodopa, used to treat Parkinson’s disease
- Muscle relaxants such as gallamine and d-tubocurarine.
- Drug that lower blood pressure such as pentolonium and trimetaphan.
- A medicine called suxamethonium (a muscle relaxant used in operations). There is an increased risk of hyperpyrexia.
- Theophylline, used to treat asthma
- Morphine, used for pain relief
- Chlorpromazine, used to treat mental illness
- Ergometrine or oxytocin, used to control bleeding in the uterus or to induce labour
- Antipsychotic medicines
- Monoamine oxidase inhibitors (MAOIS), used to treat depression. There should be stopped 2 weeks before surgery
- Antibiotics

Pregnancy and breast-feeding and fertility
Halothane can weaken the muscles of the uterus and might increase the risk of severe bleeding after delivery.
If you are pregnant or think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. You should not receive Halothane if you are pregnant unless it is essential. Traces of halothane have been found in breast milk, if you have been breastfeeding, tell your doctors, you will be advised to stop for at least 24 hours after being given Halothane.

Driving and using machines
You should not drive or use machines for at least 24 hours after you have had a general anaesthetic. Even then, you should not drive or operate machinery if you think you have not fully recovered from the effects of the anaesthetic.

3. How Halothane will be given
Halothane will be given by a trained anaesthetist in a surgery or hospital. A special piece of equipment is used to deliver halothane as a gas in the air, which you will breathe in.

- Your anaesthetist will determine the amount you receive as the effect of halothane varies between people. The anaesthetist will constantly monitor your condition.
- If your child is given halothane, hospital staff will check the electrical pattern of their heart, their blood pressure and their blood gases throughout the operation. The anaesthetist will consider factors which could affect these measures, such as the level of oxygen or carbon dioxide in their blood and other medicines being used.

Emergency use of Halothane
In an emergency you may have been given halothane and received this leaflet afterwards.

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

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

Tell your doctor immediately if you develop any symptoms of jaundice.
- Damage to the liver. This may show itself as jaundice with a yellowing of the skin or whites of the eyes. The number of white blood cell may also be increased. Very rarely the damage may be severe or even fatal. The risk of liver damage increases with repeated use of halothane or if you have had a bad reaction to anaesthetics in the past.
- A condition known as malignant hyperpyrexia. Halothane, like other general anaesthetics, can cause a sudden severe increase in body temperature, which could be fatal. This condition tends to run in families,
- Disturbances of the heart rhythm are very common.
- Feeling sick, being sick or feeling shivery after the operations are common, mild side effects.
- Cardiac arrest.
- Kidney failure, sometimes with liver failure. If you experience these or any other side effect not listed in this leaflet tell you doctor or nurse.

Like other general anaesthetics, halothane might occasionally cause some unwanted effects during your operation. These include breathing difficulties, low blood pressure, irregular or slow heartbeat or too mush muscle relaxation. These are rarely serious, as your anaesthetist will quickly deal with any problems that arise during your operation.

**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 the the national reporting system listed below.

**United Kingdom**
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 Halothane**
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 label ‘EXP’. The expiry date refers to the last day of that month.
Halothane will be stored by the hospital in a dark place below 25°C.

**6. Contents of the pack and other information**
**What Halothane contains**
- The active substance is Halothane. There are no other ingredients.

**What Halothane looks like and contents of the pack**
- Halothane is a clear liquid available in 250ml amber glass bottles

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder**
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The following information is intended for healthcare professionals only:

TECHNICAL LEAFLET

HALOTHANE
100% Inhalation Vapour, Liquid

Please read this information carefully before using Halothane 100% Inhalation Vapour, Liquid. Further information is contained in the Summary of Product Characteristics.

Presentation
Halothane 100% Inhalation Vapour, Liquid is a clear liquid used in a vapouriser to produce an inhalation gas.
The active ingredient is Halothane 100% v/v supplied in 250ml amber glass bottles

Indications
Halothane 100% Inhalation Vapour, Liquid is a general anaesthetic used in inhalation anaesthesia.
Use of halothane in paediatric dental anaesthesia should be restricted to hospitals only.

Posology and Method of Administration

Adults
Induction: Anaesthesia may be induced with 2 to 4% v/v of halothane in oxygen or mixtures of nitrous oxide and oxygen. Induction may also be started at a concentration of 0.5% v/v and increased gradually to the required level.
Maintenance: Anaesthesia is maintained with concentrations of 0.5 to 2% depending on the flow rate used; the lower concentration is usually suitable for the elderly.

Children:
For induction in children a concentration of 1.5 to 2% v/v has been used.

Elderly:
Elderly patients tend to require less halothane than adults but the actual dose is dependent on the patient's physical state

Contraindications
Hypersensitive to halothane or to other halogenated agents
History of unexplained jaundice or pyrexia after a previous exposure to halothane is an absolute contraindication to its future use in that patient.

Halothane is contraindicated in patients with known, or suspected, genetic predisposition to malignant hyperpyrexia.
Children under 18 years undergoing dental procedures outside hospital

Special warnings and precautions for use
Halothane can induce liver damage. Minor changes in serum aminotransferase activity have been reported to occur in up to 30% of patients. The incidence of severe liver damage (jaundice, which may lead to hepatic failure as a consequence of massive hepatic cell necrosis) is much rarer but cases requiring liver transplants and fatalities have been reported. The risk of developing hepatic failure appears to be greatly increased by repeated exposure to halothane. Although short intervals of time between exposures are likely to increase the risk of hepatotoxicity, even long intervals between exposure may not reduce the risks, since some patients have developed severe reactions to halothane given many years after the previous exposure. Other risk factors for hepatotoxicity include female gender, obesity, middle age and a history of drug allergy. On the information presently available, the following precautions should be taken:

- A careful anaesthetic history is to be taken from patients due to undergo anaesthesia in order to determine whether exposure to halothane took place and the nature of any adverse reaction to this agent.
- History of unexplained jaundice or pyrexia after a previous exposure to halothane is an absolute contraindication to its future use in that patient.
- Further exposure to halothane within three months is to be avoided unless there are overriding
reasons for its re-use.

- Patients who have exhibited adverse reactions to halothane should be informed and strictly instructed to alert their physician. Details of the reaction should be entered on the patient's medical records.

A rise in CSF and/or intracranial pressure might occur during neurosurgery, the effects of which may be mitigated by the use moderate hyperventilation.

Halothane reduces uterine muscle tone during pregnancy and generally its use is not recommended in obstetrics because of the increased risk of postpartum haemorrhage.

As with other agents of this type, halothane anaesthesia has been shown to trigger a skeletal muscle hypermetabolic state leading to high oxygen demand and the clinical syndrome known as malignant hyperpyrexia. This is more common when halothane is coadministered with suxamethonium. The syndrome includes nonspecific features such as hypercapnia, muscle rigidity, tachycardia, tachypnoea, cyanosis, arrhythmias and unstable blood pressure. An increase in overall metabolism may be reflected in an elevated temperature. Treatment includes discontinuation of triggering agents, administration of dantrolene sodium and application of supportive therapy.

During the induction of halothane anaesthesia, a moderate fall in blood pressure commonly occurs. (Halothane lowers arterial blood pressure in a dose-dependent manner). The pressure tends to rise when the vapour concentration is reduced to maintenance levels, but it usually remains steady below the preoperative level. This hypotensive effect is useful in providing a clear operating field and a reduction in haemorrhage. However, if necessary, intravenous doses of methoxamine (5 mg are usually adequate) can be given to counteract the fall in blood pressure.

Anaesthesia with halothane may be associated with bradycardia, which may augment its hypotensive effect. The intravenous administration of an anticholinergic agent before induction or during maintenance of anaesthesia should be considered, especially in situations where vagal tone is likely to be predominant or when halothane is used in conjunction with other agents likely to cause a bradycardia.

Halothane should be used with caution in patients with:
- Phaeochromocytoma
- Renal failure
- Pre-existing liver disease
- Myasthenia gravis
- Porphyria

Paediatric population
Arrhythmias are very common in children anaesthetised with halothane. Children anaesthetised with halothane should have ECG, blood pressure, oxygen saturation and end tidal CO\textsubscript{2} monitoring in a setting where full resuscitative equipment is available and with staff fully trained in the resuscitation of children. The presence of additional arrhythmogenic factors especially hypoxia and CO\textsubscript{2} retention, use of sympathomimetics (see 'Interactions'), and other factors which may stimulate the sympathetic nervous system should also be taken into account. Thus, to prevent hypoxia, inhalational anaesthetics are given with concentrations of oxygen greater than 21%.

Use of inhaled anaesthetic agents has been associated with very rare increases in serum potassium levels that have resulted in cardiac arrhythmias and death in children during the postoperative period. The condition has been described in patients with latent as well as overt neuromuscular disease, particularly Duchenne muscular dystrophy. Use of suxamethonium has been associated with most, but not all of these cases. These patients showed evidence of muscle damage with increased serum creatine kinase concentration and myoglobinuria. These patients did NOT have classical signs of malignant hyperthermia such as muscle rigidity, rapid increase in body temperature, or increased oxygen uptake and carbon dioxide production. Prompt and vigorous treatment for hyperkalaemia and arrhythmias is recommended. Subsequent evaluation for latent neuromuscular disease is indicated.
Fertility, pregnancy and lactation:

Pregnancy:
There is no clear evidence in animals that halothane is safe in early pregnancy. Avoid, unless its use is essential.

Halothane reduces uterine muscle tone during pregnancy and generally its use is not recommended in obstetrics because of the increased risk of postpartum haemorrhage.

Breastfeeding:
Traces of halothane have been detected in breast milk. Breast-feeding should be withheld for 24 hours after halothane anaesthesia.

Effects on ability to drive and use machines
Patients should not drive, or operate machinery, until fully recovered; i.e. for at least 24 hours after receiving halothane.

Interactions with other medicinal products and other forms of interaction
The incidence of cardiac arrhythmias may be increased when adrenaline, most other sympathomimetics (e.g. methylphenidate), and theophylline are used concurrently with halothane. There is also an increased risk of hypertension when volatile liquid anaesthetics are given with methylphenidate. The use of beta-adrenoceptor antagonists during halothane anaesthesia is at the discretion of the anaesthetist. The risk of arrhythmias is also increased if halothane is used in patients receiving dopaminergics (e.g. levodopa).

Muscle relaxants: All commonly used muscle relaxants may be used in conjunction with halothane, but, as halothane potentiates the actions of gallamine and d-tubocurarine, the doses of these muscle relaxants must be reduced. The association of d-tubocurarine with halothane may lead to a marked fall in blood pressure.

Ganglion blocking agents: Potentiation occurs between halothane and hypotensive agents such as pentolinium and trimetaphan. These drugs must be used in reduced dosage when administered in conjunction with halothane.

Aminoglycoside antibiotics: Halothane, along with all other general anaesthetics, may interact with aminoglycoside antibiotics resulting in respiratory depression. This effect may be potentiated by the concurrent use of a neuromuscular blocker.

Suxamethonium: The concurrent use of suxamethonium with halothane is not advisable due to the increased possibility of hyperpyrexia.

Morphine and chlorpromazine increase the depressant effects of halothane on respiration.

The effects of both ergometrine and oxytocin on the parturient uterus are diminished by halothane.

An enhanced hypotensive effect may be seen when general anaesthetics are given with adrenergic neurone blockers, alphablockers, antipsychotics or calcium channel blockers.

Monoamine oxidase inhibitors (MAOIs) should normally be stopped 2 weeks before surgery because of hazardous interactions between general anaesthetics and MAOIs.

Pharmaceutical Information

Excipients
None

Incompatibilities
Vaporiser: Halothane must not be used in the EMO ether vaporiser as it attacks the metal; a vaporiser
specially constructed for halothane should be used.

**Shelf-life**
60 months

**Storage Precautions**
Store in a dark place below 25°C. Keep well closed.

**Nature of Container**
Amber glass bottle with red collar and an aluminium gold lacquered cap fitted with a polythene wad.
Pack size: 250 ml

**Special precautions for disposal and other handling :**
Please refer to 'Posology and Method of Administration'.

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