

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Halothane-Vet 100% Inhalation vapour, liquid.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Halothane 100% w/w. (Includes Thymol 0.01% w/w as a preservative).

For full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Inhalation vapour, liquid.
A clear colourless volatile liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Horses, domestic animals, and non-domesticated mammals, birds and reptiles.

4.2 Indications for use (specifying the target species)

The induction and maintenance of general anaesthesia.

4.3 Contraindications

None.

4.4 Special warnings (for each target species)

Malignant hyperthermia has been reported in the dog and horse but its incidence is rare.

4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to the animals

(i) Special precautions for use in animals

During the induction of anaesthesia, a moderate fall in blood pressure commonly occurs. The pressure tends to rise when the vapour concentration is reduced to maintenance levels, but it usually remains steady below the pre-operative level.

(ii) Special precautions to be taken by the person administering the medicinal product to the animals

Do not breathe vapour.
Avoid contact by mouth.

Pregnant and breast-feeding women should avoid exposure to the product and should avoid operating rooms and animal recovery areas.

Use with efficient scavenging equipment. To protect the environment, the use of

charcoal filters with such equipment is to be encouraged to reduce the amounts discharged to the atmosphere.

Ensure that the operating room has an adequate active extraction system.

Care should be taken when dispensing Halothane, with any spillage removed immediately using inert and absorbent material e.g. sawdust.

Use cuffed endotracheal intubation whenever possible for the maintenance of general anaesthesia with Halothane.

Where possible, vaporisers should be filled outside the operating theatre or outdoors.

Avoid using masking procedures for prolonged induction and maintenance of general anaesthesia.

Wash any splashes from skin and eyes immediately.

Induction/Recovery areas should be well ventilated.

All scavenging/extraction systems must be adequately maintained and anaesthetic equipment regularly checked for leaks.

Halothane can induce liver damage. This is an idiosyncratic response very occasionally seen after repeated exposure.

In the event of severe acute accidental exposure remove the operator from the source of exposure, seek urgent medical assistance and show this label.

Advice to doctors: Maintain a patent airway and give symptomatic and supportive treatment. Note that the use of adrenaline and catecholamines is contra-indicated since they may cause severe cardiac dysrhythmia.

4.6 Adverse reactions (frequency and seriousness)

Halothane delays involution of the uterus following caesarean section. Ecboic drugs may need to be given to the mother after delivery of the off-spring.

4.7 Use during pregnancy, lactation or lay

May be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Premedicants are frequently used to facilitate the induction of anaesthesia and reduce the required dosage of induction agents (such as short acting barbiturates) and inhalation agents. Particular care should be exercised in animals premedicated with alpha-2-adrenoceptor agonists.

Halothane sensitises the heart to the catecholamines and the use of adrenaline should be avoided where possible.

Halothane potentiates the action of non-depolarising muscle relaxants such as

gallamine and d-tubocurarine and dosage of these agents should be reduced.

4.9 Amount(s) to be administered and administration route

For administration by inhalation. Halothane may be administered using either open, semi-open or closed circuit systems. Closed circuit systems and endotracheal intubation should be used whenever possible.

Small Animals

Induction: Anaesthesia is induced by using a concentration of Halothane in the range 2-4%. Alternatively a short acting induction agent (such as thiopentone sodium) may be used, and it is to be preferred in large or excitable subjects.

Maintenance: Once a surgical plane of anaesthesia is reached, it may be maintained by a reduced concentration of between 0.5 and 2% depending on the size of the animal and the method used.

Horses Not Intended for Human Consumption

Induction: It may be possible to administer Halothane to a standing foal using a Cox mask, but as it is not normally practicable to induce anaesthesia in large animals using Halothane, induction should be by the use of a short-acting intravenous agent such as thiopentone sodium. A concentration of 5-8% Halothane may then be used to complete the induction of surgical anaesthesia in 5-10 minutes.

Maintenance: Anaesthesia may be maintained by the administration of 0.8-2% Halothane vapour. Depending on the fresh gas flow-rate, to give this concentration to the animal it is usually necessary to deliver 1.5-5% from any out-of-circuit vapouriser, at least for the first hour.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Halothane causes dose related respiratory and cardiovascular depression, and respiration and pulse character should be monitored. Respiratory arrest should be treated by assisted ventilation with air, or preferably oxygen supplementation. It is important that a patent airway be maintained and adequate tissue oxygenation achieved throughout the period of anaesthesia. Should cardiac arrest occur, full cardiopulmonary resuscitation methods should be applied.

4.11 Withdrawal period(s)

Not to be used in animals intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national Horse Passport legislation.

5. PHARMACOLOGICAL PROPERTIES

ATC Vet Code: QN01AB01

5.1 Pharmacodynamic properties

Halothane produces rapid reversible anaesthesia by depression of the central nervous system. Respiration is decreased in amplitude and frequency, and the blood pressure is lowered. The heart rate is decreased.

The potency of an inhalation anaesthetic is determined largely by its oil: gas partition coefficient, while the uptake is governed by the blood: gas partition coefficient. Halothane has high lipid solubility and relatively poor solubility in blood, resulting in a potent anaesthetic agent with a rapid onset and recovery.

5.2 Pharmacokinetic properties

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thymol

6.2 Major incompatibilities

None known.

6.3 Shelf life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time.

Shelf life of the veterinary medicinal product as packaged for sale:
5 years

6.4 Special precautions for storage

Do not store above 25°C.
Store in tightly closed original container. Protect from light.

6.5 Nature and composition of immediate packaging

Type III amber glass bottles containing 250ml of a clear, colourless, volatile liquid.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Merial Animal Health Limited
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Sandringham House
Harlow Business Park
Harlow
Essex, CM19 5TG UK

8. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4027
VPA 10857/26/1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

UK: 04 October 2003
IRE: 01 October 2005

10. DATE OF REVISION OF THE TEXT

July 2008

11. ANY OTHER INFORMATION REQUIRED BY THE SECRETARY OF STATE

Not applicable.