

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HALOTHANE-VET 100% Inhalation vapour

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Liquid halothane 100% w/w

3. PHARMACEUTICAL FORM

Inhalation vapour

4. PACKAGE SIZE

250ml

5. TARGET SPECIES

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

6. INDICATION(S)

A volatile anaesthetic for the induction and maintenance of general anaesthesia by inhalation in domestic animals and non-domestic mammals, birds and reptiles.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

8. WITHDRAWAL PERIOD

9. SPECIAL WARNINGS

See accompanying directions.

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.

Bottle Label MUST be read BEFORE USE.

10. EXPIRY DATE

EXP Date:

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

UK only:

	Vm 08327/4027
POM-V	
	To be supplied only on veterinary prescription

For animal treatment only.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Merial Animal Health Ltd.
Sandringham House,
Harlow Business Park,
Harlow, Essex, CM19 5TG
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4027

17. MANUFACTURER’S BATCH NUMBER

LOT NO:

18. FURTHER INFORMATION

MNF:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (BOTTLE LABEL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HALOTHANE – VET 100% Inhalation vapour

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Liquid Halothane 100% w/w

3. PHARMACEUTICAL FORM

Inhalation vapour

4. PACKAGE SIZE

250ml

5. TARGET SPECIES

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

6. INDICATION(S)

A volatile anaesthetic for the induction and maintenance of general anaesthesia by inhalation in horses, domestic animals and non-domesticated mammals, birds and reptiles.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

8. WITHDRAWAL PERIOD

9. SPECIAL WARNINGS

See accompanying directions.

Not to be used in animals intended for human consumption.

Bottle Label MUST be read BEFORE USE.

10. EXPIRY DATE

EXP. DATE:

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

UK only:

POM-V
Vm 08327/4027 To be supplied only on veterinary prescription

For animal treatment only.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4027

17. MANUFACTURER’S BATCH NUMBER

LOT NO:

18. FURTHER INFORMATION

MNF:

PACKAGE LEAFLET FOLD-OUT BOTTLE LABEL FOR: HALOTHANE-VET

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder:

Merial Animal Health Ltd

Sandringham House
Harlow Business Park
Harlow, Essex, CM19 5TG UK

Manufacturer for the batch release:

Piramal Healthcare UK Limited

Whalton Road, Morpeth,
Northumberland, NE 61 3YA,
United Kingdom.

and

Merial S.A.S

4, Chemin du calquet
31300 Toulouse, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

HALOTHANE – VET 100% Inhalation vapour

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Liquid Halothane 100% w/w
0.01% w/w thymol

4. INDICATION(S)

A volatile anaesthetic for the induction and maintenance of general anaesthesia by inhalation in horses, domestic animals and non-domesticated mammals, birds and reptiles.

5. CONTRAINDICATIONS

Not for use in animals intended for human consumption.

6. ADVERSE REACTIONS

7. TARGET SPECIES

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

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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. 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.

9. ADVICE ON CORRECT ADMINISTRATION

Whilst in the liquid phase Halothane must not be diluted or contaminated. However, in the vapour phase it may be administered together with oxygen or a mixture of nitrous oxide and oxygen.

Thymol 0.01% is included as a preservative according to BP requirements. As Halothane vapourises, the concentration of thymol increases and this can cause vapouriser controls to stick and ports to be occluded. Periodic servicing and recalibration of precision vapourisers is thus essential to ensure delivery of known concentrations of Halothane vapour.

10. 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.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Protect from light.

Store in tightly closed original container.

12. SPECIAL WARNING(S)

Warnings: Halothane potentiates the action of non-depolarising muscle relaxants such as gallamine and d-tubocurarine and dosage of these agents should be reduced. Premedicants are frequently used to facilitate the induction of anaesthesia and reduce the required dosage of induction agents (such as short acting barbiturates). Particular care should be exercised in animals premedicated with alpha-2- adrenoceptor agonists.

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. 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 oxygenation achieved throughout the period of anaesthesia. Should cardiac arrest occur, full cardiopulmonary resuscitation methods should be applied. Halothane sensitises the heart to the catecholamines and the use of adrenaline should be avoided where possible, otherwise adrenaline doses should be minimal. Halothane delays involution of the uterus following caesarean section. Ecboic drugs may need to be given to the mother after delivery of the offspring.

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

Operator warnings

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 remove 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, vapourisers 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

UK only:

POM-V
Vm 08327/4027
To be supplied only on veterinary prescription

For animal treatment only.

Keep out of the reach and sight of children.

Bottle Label MUST be read BEFORE USE.

HALOTHANE VET, to which 0.01% w/w thymol is added as a stabilising agent, is non-flammable and non-explosive when mixed with oxygen. It is an almost colourless, volatile liquid with a distinctive pleasant odour.

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

Approved: 16/08/2017

A handwritten signature in black ink, appearing to read 'J. Berg', is written below the approval date.