

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE (250 ml and 100 ml
Carton)**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Isoflurane-Vet 100% w/w Inhalation Vapour, liquid

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains isoflurane 100% w/w

3. PHARMACEUTICAL FORM

Inhalation vapour.

4. PACKAGE SIZE

250 ml

100 ml

5. TARGET SPECIES

Horses, Dogs, Cats and Ornamental Birds.

6. INDICATIONS

See package leaflet for directions and warnings.

7. METHOD AND ROUTES OF ADMINISTRATION

See package leaflet for directions and warnings.

8. WITHDRAWAL PERIOD

Not to be used in horses 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.

9. SPECIAL WARNINGS, IF NECESSARY

See package leaflet for directions and warnings.

Non flammable. Non explosive.

Wash hands after use.

10. EXPIRY DATE

Expiry:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Store in tightly closed original container.

Protect from direct sunlight.

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

See package leaflet for directions and warnings.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [*Distribution category*]

For animal treatment only.

POM-V

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

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4131

17. MANUFACTURER’S BATCH NUMBER

Batch:

18. ADDITIONAL INFORMATION

To be supplied only on veterinary prescription.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (250 ml and 100 ml label)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Isoflurane-Vet 100% w/w Inhalation Vapour, liquid

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains isoflurane 100% w/w

3. PHARMACEUTICAL FORM

Inhalation vapour.

4. PACKAGE SIZE

250 ml

100 ml

5. TARGET SPECIES

Horses, Dogs, Cats and Ornamental Birds.

6. INDICATIONS

See package leaflet for directions and warnings.

7. METHOD AND ROUTES OF ADMINISTRATION

See package leaflet for directions and warnings.

8. WITHDRAWAL PERIOD

Not to be used in horses intended for human consumption.

9. SPECIAL WARNINGS, IF NECESSARY

See package leaflet for directions and warnings.

Non flammable. Non explosive.

Wash hands after use.

10. EXPIRY DATE

Expiry:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Store in tightly closed original container.

Protect from direct sunlight.

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

See package leaflet for directions and warnings.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [*Distribution category*]

For animal treatment only.

POM-V

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

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER

Vm 08327/4131

17. MANUFACTURER’S BATCH NUMBER

Batch:

18. ADDITIONAL INFORMATION

To be supplied only on veterinary prescription.

PACKAGE LEAFLET FOR: Isoflurane-Vet 100% w/w Inhalation Vapour, liquid

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

Marketing Authorisation Holder:

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer responsible for batch release:

Piramal Critical Care B.V.
Rouboslaan 32 (ground floor), 2252 TR
Voorschoten
The Netherlands

AND

Piramal Critical Care Limited
Suite 4, Ground Floor,
Heathrow Boulevard - East Wing,
280 Bath Road, West Drayton,
UB7 0DQ
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Isoflurane-Vet 100% w/w Inhalation Vapour, liquid

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

4. INDICATIONS

USES

For the induction and maintenance of general anaesthesia in horses, dogs, cats, and ornamental birds.

5. CONTRAINDICATIONS

The agent should not be used in animals with a known sensitivity to isoflurane or other halogenated or other inhalational agents

6. ADVERSE REACTIONS

Isoflurane sensitises the myocardium to the dysrhythmogenic effects of circulating catecholamines in the dog but to a lesser extent than other halogenated anaesthetic agents.

7. TARGET SPECIES

Horses, dogs, cats and ornamental birds.

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

Premedication

The premedication regimen should be selected which is appropriate to the animal, its clinical condition and the procedure to be performed. The administration of isoflurane has been shown to be compatible with the commonly used agents such as acepromazine, opioid analgesics, alpha 2 – adrenoreceptor agonists and anticholinergic drugs.

Induction

Induction of anaesthesia in the adult horse is usually achieved by the use of a barbiturate, ketamine and/or muscle relaxant, and all of these agents have been shown to be compatible with the administration of isoflurane. In the dog and cat, anaesthesia is normally induced with a barbiturate or propofol, and these agents have also been shown to be compatible with isoflurane. In cats and in birds, ketamine may also be used for the induction of anaesthesia.

Inspired Concentration

In view of the fact that Isoflurane is a relatively potent and rapidly acting anaesthetic agent, it is essential that the delivered concentration is known. Hence an accurately calibrated, temperature compensated and agent specific vaporiser should be used. However, it has on some occasions been satisfactorily administered from a simple in-circuit vaporiser.

Induction of Anaesthesia with Isoflurane

Horses

Under normal conditions, anaesthesia would only be induced with isoflurane in foals. This can be achieved using concentrations of 3 to 5 per cent isoflurane in either oxygen or in nitrous oxide/oxygen (in a ratio of 2:1) as a carrier gas. This may be administered by nasal endotracheal tube, nasal insufflation or by mask. This technique will normally produce general anaesthesia within a period of 5 to 10 minutes when oral endotracheal intubation may be performed. Once anaesthesia has been induced by an intravenous agent in the mature horse, concentrations of 3 to 5 per cent of isoflurane should be administered initially to ensure an adequate transition to Isoflurane anaesthesia.

Dogs and Cats

Anaesthesia can readily be achieved in the premedicated dogs and cats with isoflurane at concentrations of between 2 and 4 per cent. Either oxygen alone or nitrous oxide/oxygen in a ratio of 2:1 may be used as a carrier gas and administered by mask. When anaesthesia is induced by the intravenous route, concentrations of

isoflurane of up to 3 per cent should be administered to achieve a smooth transition to Isoflurane anaesthesia.

Birds

Anaesthesia can be induced in birds by administration of isoflurane in oxygen at delivered concentrations of between 2 and per cent. This should be administered by mask which can be readily adapted from those used in the small domestic animal.

Maintenance of Anaesthesia

The concentrations of isoflurane necessary to maintain anaesthesia in all species are lower than those required to induce anaesthesia. This is obviously, related to the MAC value of the agent in a particular species. As a general guideline, an end-tidal concentration of 1.5 MAC will be adequate for the maintenance of anaesthesia under most conditions.

Horses

Delivered concentrations from the vaporiser of up to 3 per cent isoflurane in oxygen are normally required to maintain surgical anaesthesia in the horse.

Dogs and cats

Delivered concentrations from the vaporiser of up to 2.5 per cent isoflurane in oxygen are required to maintain surgical anaesthesia in the dog and cat. This may be reduced to a figure of up to 2 per cent when nitrous oxide and oxygen are used as a carrier gas.

Birds

Delivered concentrations from the vaporiser of up to 2.5 per cent isoflurane in oxygen are normally required to maintain anaesthesia in birds.

The level of arterial blood pressure during maintenance of anaesthesia is an inverse function of the administered isoflurane concentration in the absence of other complicating factors. Excessive degrees of hypotension, unless they are specifically related to a reduced circulating blood volume, may be due to depth of anaesthesia and, in such a situation, may be corrected by reducing the delivered concentration of isoflurane. However, it may sometimes be necessary in the horse, as with other inhalational anaesthetic agents, to administer an inotropic drug.

Recovery from isoflurane is normally uneventful, but it may be more reactive in the horse.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIODS

Not to be used in horses 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. Store in tightly closed original container. Protect from direct sunlight.

Keep out of reach of children.

12. SPECIAL WARNINGS

Levels of anaesthesia can be altered easily and rapidly with isoflurane. Hence it is recommended that only vaporisers which are reliable and produce a predictable concentration of isoflurane should be employed.

Isoflurane produces a dose-related depression of respiration and, with increasing depth of anaesthesia, both tidal volume and respiratory rate are decreased. This depression is partially reversed by surgical stimulation even at deep levels of anaesthesia. Respiratory activity should be monitored closely and assisted or controlled when necessary.

Administration of Isoflurane will also produce a dose-related depression of arterial blood pressure, although this is raised by surgical stimulation. Any excessive depression of the arterial blood pressure, unrelated to hypovolemia is normally related to the depth of anaesthesia. It can usually be corrected by reducing the administered concentration of isoflurane although it may be necessary, in horses, to administer an inotropic agent such as dobutamine. However, the heart rate is normally stable and, by the use of controlled ventilation, the paCO_2 can be maintained within the normal range as can cardiac output. Spontaneous ventilation with isoflurane anaesthesia can lead to hypercapnia with an accompanying increase in heart rate and cardiac output greater than that observed with controlled ventilation.

Isoflurane anaesthesia is normally accompanied by muscle relaxation, that may be adequate for most surgical procedures. However, if profound muscle relaxation is required, and to initiate intermittent positive pressure ventilation for thoracic surgery, muscle relaxants may be used. All of the commonly available non-depolarising muscle relaxants are potentiated by isoflurane. Hence the duration of neuromuscular blockade will be longer than with most other anaesthetic techniques. Whilst the anticholinesterase drugs will reverse the non-depolarising neuromuscular block, they do not influence the neuromuscular depression produced by isoflurane.

In the event of overdosage, cease isoflurane administration, check the airway and, if an endotracheal tube is not in place, one should be inserted. Intermittent positive pressure ventilation with oxygen should be initiated.

When using isoflurane to anaesthetise an animal with a head injury, consideration should be given as to whether artificial ventilation is appropriate to maintain normal CO₂ levels, so that cerebral blood flow does not increase.

Operator Warnings

Wash hands after use.

Wash any splashes from skin and eyes immediately and avoid contact with the mouth.

Pregnant and breast-feeding women should avoid exposure to the product.

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

Do not breathe vapour. Users should consult their relevant National Authority for advice on Occupational Exposure Standards for isoflurane.

Operating rooms should have an adequate active extraction system, and induction/recovery areas should be well ventilated, in order to ensure that atmospheric concentrations of isoflurane stay below the OES.

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

Avoid using masking procedures for prolonged induction and maintenance of general anaesthesia. Use cuffed endotracheal intubation when possible for the administration of isoflurane during maintenance of general anaesthesia.

Although Isoflurane-Vet has a low potential for damage to the atmosphere, it is considered good practice to use charcoal filters with scavenging equipment.

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

Halogenated anaesthetic agents may induce liver damage. In the case of isoflurane this is an idiosyncratic response very rarely seen after repeated exposure.

Advice to doctors: Maintain a patent airway and give symptomatic and supportive treatment.

Doctors should be aware that adrenaline and catecholamines may cause cardiac dysrhythmia.

Isoflurane has been reported to interact with dry carbon dioxide absorbents to form carbon monoxide. In order to minimise the risk of this rebreathing circuits, and the possibility of elevated carboxyhaemoglobin levels, absorbents should not be allowed to dry out.

For Animal Treatment Only

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

POM-V

Vm 08327/4131

To be supplied only on veterinary prescription.

PRESENTATION

Isoflurane is a volatile, non-flammable, non-explosive, clear, colourless, stable liquid, with a mildly pungent, musty ethereal odour. Chemically, it is 1-chloro-2,2,2-trifluoroethyl difluoromethyl ether. It has purity greater than 99.9% and contains no additives or chemical stabiliser.

MAC (Minimum Alveolar Concentration) is 1.31% in adult horses, 1.28% in dogs, 1.68% in cats and 1.34% in birds.

Isoflurane does not decompose in the present of soda lime, and does not react with metals commonly used in anaesthetic equipment.

PACKAGE QUANTITIES

Bottles of 100 ml and 250 ml.

FURTHER INFORMATION

Reproduction studies on the common laboratory animal species have demonstrated no evidence of foetal malformation or effect on fertility. Equivalent data in domestic species have not been established.

Revised: May 2019
AN: 01791/2018

Approved: 09 May 2019

A handwritten signature in black ink, appearing to read "J. Muell", with a horizontal line underneath the name.