

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ISOFLURANE-Vet 100% w/w Inhalation Vapour, Liquid

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Isoflurane 100% w/w

3. PHARMACEUTICAL FORM

Inhalation vapour, liquid.

For full list of excipients, see section 6.1

4. CLINICAL PARTICULARS

4.1 Target species

Dogs, cats, horses and ornamental birds.

4.2 Indications for use, specifying the target species

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

4.3 Contra-indications

Do not use in animals with a known sensitivity to Isoflurane or other inhalational agents.

4.4 Special warnings for each target species

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.

In cats, intubation may be assisted by use of lidocaine spray to avoid laryngospasm.

4.5 Special precautions for use

(i) Special precautions for use in animals

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 pa CO₂ 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, which 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 anti-cholinesterase drugs will reverse the non-depolarising neuromuscular block, they do not influence the neuromuscular depression produced by Isoflurane.

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

- Wash any splashes from the skin and eyes immediately and avoid contact with the mouth.
- 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.
- Pregnant and breast-feeding women should avoid exposure to the product.
- 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.
- **In the event of severe 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.
- Although Isoflurane Vet has a low potential for damage to the atmosphere, it is considered good practice to use charcoal filters with scavenging equipment.
- Halogenated anaesthetic agents may induce liver damage. In the case of isoflurane this is an idiosyncratic response very rarely seen after repeated exposure.

4.6 Adverse reactions (frequency and seriousness)

Isoflurane sensitises the myocardium to the dysrhythmogenic effects of circulating catecholamine in the dog, but to a lesser extent than other halogenated anaesthetic agents. Side effects include respiratory depression, hypotension and vasodilation.

Malignant hyperthermia with halogenated agents has been reported in horses and dogs.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

Isoflurane is compatible with the commonly used premedicant agents such as acepromazine, opioid analgesics, alpha 2 – adrenoceptor agonists and anti-cholinergic drugs.

Isoflurane is also compatible with barbiturates, ketamine and muscle relaxants in the horse, and with barbiturates and propofol in the dog.

4.9 Amounts to be administered and administration route

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.

Premedication

The premedication regimen should be selected which is appropriate to the animal, its clinical condition and the procedure to be performed.

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 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 4%. This should be administered by mask which can be readily adapted from those used in the small domestic animal.

Maintenance

The concentration 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 vapouriser of up to 3 per cent Isoflurane in oxygen are normally required to maintain surgical anaesthesia in the horse.

Dogs and cats

Delivered concentrations 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 vapouriser of up to 2.5% Isoflurane in oxygen is 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, though it may be more reactive in the horse.

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

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.

4.11 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.

5. PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Isoflurane is a general inhalational anaesthetic, which provides rapid induction of anaesthesia and also rapid recovery. The MAC (Minimum Alveolar Concentration), the standard measure of potency for anaesthetics, is 1.28% for dogs, 1.31% for horses, 1.68% for cats and 1.34% for birds.

Isoflurane shows very low solubility in blood and body tissues, and this results in the rapid development of an alveolar partial pressure sufficient to cause anaesthesia. Biotransformation of Isoflurane occurs only to an extremely limited extent.

ATC Vet Code: QN01AB06

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Major incompatibilities

Isoflurane has been reported to interact with dry Carbon Dioxide absorbents to form Carbon Monoxide. In order to minimise the risk of this in rebreathing circuits, and the possibility of elevated carboxyhaemoglobin level, absorbants should not be allowed to dry out.

6.3 Shelf-life

5 years.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Amber coloured round, Type III, screw-capped bottles in either 100 ml or 250 ml pack size. The closure is a black screw cap fitted with a polyethylene cone. The bottles are provided with LDPE purple coloured collars.

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

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4131

9. DATE OF FIRST AUTHORISATION

15 November 1996

10. DATE OF REVISION OF THE TEXT

August 2019

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke extending to the right.

Approved 28 August 2019