

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box with 1 bottle of 100 ml or 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetflurane 1000 mg/g Inhalation vapour, liquid

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 1000 mg/g isoflurane.

3. PHARMACEUTICAL FORM

Inhalation vapour, liquid

4. PACKAGE SIZE

100 ml

250 ml

5. TARGET SPECIES

Horses, dogs, cats, ornamental birds, reptiles, rats, mice, hamsters, chinchillas, gerbils, guinea pigs and ferrets.

6. INDICATION(S)

Induction and maintenance of general anaesthesia.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Horse: withdrawal period for meat and offal : 2 days.

The product should not be used for the treatment of mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP : {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC S.A.
1ère avenue – 2065m – L.I.D.
06516 Carros
FRANCE

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Batch : {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle label 100 ml

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EXP : {month/year}

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1ère avenue – 2065m – L.I.D.
06516 Carros
FRANCE

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Batch : {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle label 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetflurane 1000 mg/g Inhalation vapour, liquid

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 1000 mg/g isoflurane.

3. PHARMACEUTICAL FORM

Inhalation vapour, liquid

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

Read the package leaflet before use.

6. INDICATION(S)

Induction and maintenance of general anaesthesia.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Horse: withdrawal period for meat and offal : 2 days.
The product should not be used for the treatment of mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

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10. EXPIRY DATE

EXP : {month/year}

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VIRBAC S.A.
1ère avenue – 2065m – L.I.D.
06516 Carros
FRANCE

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Batch : {number}

PACKAGE LEAFLET

Vetflurane 1000 mg/g 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 and manufacturer responsible for batch release:

VIRBAC S.A.
1ère avenue – 2065m – L.I.D.
06516 Carros
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetflurane 1000 mg/g Inhalation vapour, liquid

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

Each millilitre contains:

Active substance:

Isoflurane 1000 mg/g.

Clear, colourless liquid

4. INDICATION(S)

Induction and maintenance of general anaesthesia.

5. CONTRAINDICATIONS

Do not use in case of known susceptibility to malignant hyperthermia.

Do not use in cases of known hypersensitivity to isoflurane or to other halogenated agents.

6. ADVERSE REACTIONS

Isoflurane produces hypotension and respiratory depression in a dose-related manner.

Cardiac arrhythmias and transient bradycardia have been reported only rarely.

Malignant hyperthermia has been reported very rarely in susceptible animals.

Respiratory arrest should be treated by assisted ventilation.

In the case of cardiac arrest, perform a complete cardio pulmonary resuscitation.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses, dogs, cats, ornamental birds, reptiles, rats, mice, hamsters, chinchillas, gerbils, guinea pigs and ferrets.

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

The concurrent use of sedative or analgesic drugs is likely to reduce the level of isoflurane required to produce and maintain anaesthesia. See section 12 for specific interactions.

HORSE

The MAC for isoflurane in the horse is approximately 1.31%

Premedication

Isoflurane may be used with other drugs commonly used in veterinary anaesthetic regimes. The following drugs have been found to be compatible with isoflurane: acepromazine, butorphanol, detomidine, diazepam, dobutamine, dopamine, guaiphenesin, ketamine, morphine, pethidine, thiamylal, thiopentone and xylazine. Drugs used for premedication should be selected for the individual patient. However, the potential interactions below should be noted.

Interactions

See section 12.

Induction

As it is not normally practicable to induce anaesthesia in adult horses using isoflurane, induction should be by the use of a short acting barbiturate such as thiopentone sodium, ketamine or guaiphenesin. Concentrations of 3 to 5% isoflurane may then be used to achieve the desired depth of anaesthesia in 5 to 10 minutes.

Isoflurane at a concentration of 3 to 5% in a high flow oxygen may be used for induction in foals.

Maintenance

Anaesthesia may be maintained using 1.5% to 2.5% isoflurane.

Recovery

Recovery is usually smooth and rapid.

DOG

The MAC for isoflurane in the dog is approximately 1.28%.

Premedication

Isoflurane may be used with other drugs commonly used in veterinary anaesthetic regimes. The following drugs have been found to be compatible with isoflurane: acepromazine, atropine, butorphanol, buprenorphine, bupivacaine, diazepam, dobutamine, ephedrine, epinephrine, glycopyrrolate, ketamine, medetomidine, midazolam, methoxamine, oxymorphone, propofol, thiamylal, thiopentone and xylazine. Drugs used for premedication should be selected for the individual patient. However, the potential interactions below should be noted.

Interactions

See section 12.

Induction

Induction is possible by face mask using up to 5% isoflurane, with or without premedication.

Maintenance

Anaesthesia may be maintained using 1.5% to 2.5% isoflurane.

Recovery

Recovery is usually smooth and rapid.

CAT

The MAC for isoflurane in the cat is approximately 1.63%.

Premedication

Isoflurane may be used with other drugs commonly used in veterinary anaesthetic regimes. The following drugs have been found to be compatible with isoflurane: acepromazine, atropine, diazepam, ketamine, and oxymorphone. Drugs used for premedication should be selected for the individual patient. However, the potential interactions below should be noted.

Interactions

See section 12.

Induction

Induction is possible by face mask using up to 4% isoflurane, with or without premedication.

Maintenance

Anaesthesia may be maintained using 1.5% to 3% isoflurane.

Recovery

Recovery is usually smooth and rapid.

ORNAMENTAL BIRDS

Few MAC/ED₅₀ values have been recorded. Examples are 1.34% for the Sandhill crane, 1.45% for the racing pigeon, reduced to 0.89% by the administration of midazolam, and 1.44% for cockatoos, reduced to 1.08% by the administration of butorphanol analgesic.

The use of isoflurane anaesthesia has been reported for many species, from small birds such as zebra finches, to large birds such as vultures, eagles and swans.

Drug interactions/compatibilities

Propofol has been demonstrated in the literature to be compatible with isoflurane anaesthesia in swans.

Interactions

See section 12.

Induction

Induction with 3 to 5% isoflurane is normally rapid. Induction of anaesthesia with propofol, followed by isoflurane maintenance, has been reported for swans.

Maintenance

The maintenance dose depends on the species and individual. Generally, 2 to 3% is suitable and safe.

Only 0.6 to 1% may be needed for some stork and heron species.
Up to 4 to 5% may be needed for some vultures and eagles.
3.5 to 4% may be needed for some ducks and geese.
Generally, birds respond very rapidly to changes in concentration of isoflurane.

Recovery

Recovery is usually smooth and rapid.

REPTILES

The literature records isoflurane's use on a wide variety of reptiles (eg. various species of lizard, tortoise, iguanas, chameleon and snakes).

The ED₅₀ was determined in the desert iguana to be 3.14% at 35°C and 2.83% at 20°C.

Drug interactions/ compatibilities

See section 12.

Induction

Induction is usually rapid at 2 to 4% isoflurane.

Maintenance

1 to 3% is a useful concentration

Recovery

Recovery is usually smooth and rapid

RATS, MICE, HAMSTERS, CHINCHILLAS, GERBILS, GUNIEA PIGS AND FERRETS

The MAC for mice has been cited as 1.34%, and for the rat as 1.38%, 1.46% and 2.4%.

Drug interactions/ compatibilities

See section 12.

Induction

Isoflurane concentration 2 to 3%.

Maintenance

Isoflurane concentration 0.25 to 2%.

Recovery

Recovery is usually smooth and rapid.

Species	MAC (%)	Induction (%)	Maintenance (%)	Recovery
Horse	1.31	3.0 – 5.0 (foals)	1.5 – 2.5	Smooth and rapid
Dog	1.28	Up to 5.0	1.5 – 2.5	Smooth and rapid
Cat	1.63	Up to 4.0	1.5 – 3.0	Smooth and rapid
Ornamental birds	See posology	3.0 – 5.0	See posology	Smooth and rapid
Reptiles	See posology	2.0 – 4.0	1.0 – 3.0	Smooth and rapid
Rats, mice,	1.34 (mouse)			Smooth and

hamsters, chinchillas, gerbils, guinea pigs and ferrets	1.38/1.46/2.40 (rat)	2.0 – 3.0	0.25 – 2.0	rapid
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9. ADVICE ON CORRECT ADMINISTRATION

Isoflurane should be administered using an accurately calibrated vaporiser in an appropriate anaesthetic circuit, since levels of anaesthesia may be altered rapidly and easily.

Isoflurane may be administered in oxygen or oxygen/nitrous oxide mixtures. The MAC (minimal alveolar concentration in oxygen) or effective dose ED₅₀ values and suggested concentrations given below for the target species should be used as a guide or starting point only. The actual concentrations required in practice will depend on many variables, including the concomitant use of other drugs during the anaesthetic procedure and the clinical status of the patient.

Isoflurane may be used in conjunction with other drugs commonly used in veterinary anaesthetic regimes for premedication, induction and analgesia. Some specific examples are given in the individual species information.

Recovery from isoflurane anaesthesia is usually smooth and rapid. The analgesic requirements of the patient should be considered before the termination of general anaesthesia.

10. WITHDRAWAL PERIOD

Horse: withdrawal period for meat and offal : 2 days.

The product should not be used for the treatment of mares producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25 °C.

Protect from direct sunlight and heat.

Store in tightly closed original container.

Do not use this veterinary medicinal after the expiry date which is stated on the carton and bottle after "EXP". The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings

The metabolism of birds, and to an extent small mammals, is affected more profoundly by decreases in body temperature, due to high surface area to body weight ratio. Drug metabolism in reptiles is slow and highly dependent upon environmental temperature. The absorption, distribution and elimination of isoflurane are rapid, and it is eliminated largely unchanged via the lungs. These characteristics may make it suitable for groups of patients including the young or old, or those with impaired hepatic, renal or cardiac function, however anaesthetic protocols should be decided on a case by case basis.

Special precautions for use in animals

Isoflurane has little or no analgesic properties. Adequate analgesia should always be given before surgery. The analgesic requirements of the patient should be considered before general anaesthesia is ended.

The use of the product in patients with cardiac disease should be considered only after a risk/benefit assessment by the veterinarian.

It's important to monitor breathing and pulse for the frequency and its features. It's important to maintain airways free and properly oxygenate tissues during the maintenance of anaesthesia.

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.

As isoflurane is a respiratory depressant, it could be advised to monitor the respiratory rate and depth during anaesthesia.

Use during pregnancy, lactation or lay

Pregnancy:

Use only according to the benefit/risk assessment by the responsible veterinarian. Isoflurane has been safely used for anaesthesia during caesarean section in the dog and cat.

Lactation:

Use only according to the benefit/risk assessment by the responsible veterinarian

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

In case of a known hypersensitivity to isoflurane, the professional must not handle this product.

Do not breathe the vapour.

Users should consult their National Authority for advice on Occupational Exposure Standards for isoflurane.

Operating rooms and recovery areas should be provided with adequate ventilation or scavenging systems to prevent the accumulation of anaesthetic vapour. All scavenging/extraction systems must be adequately maintained.

Pregnant and breast-feeding women should not have any contact with the product and should avoid operating rooms and animal recovery areas.

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

Use cuffed endotracheal intubation when possible for the administration of this product during maintenance of general anaesthesia.

To protect the environment, it is considered good practice to use charcoal filters with scavenging equipment.

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

Wash any splashes from skin and eyes, and avoid contact with the mouth. If severe accidental exposure occurs remove the operator from the source of exposure, seek urgent medical assistance and show this label.

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

Advice to Doctors: Ensure a patent airway and give symptomatic and supportive treatment.

Note that adrenaline and catecholamines may cause cardiac dysrhythmias.

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

Interaction with other medicinal products and other forms of interaction

Concurrent inhalation of nitrous oxide enhances the effect of isoflurane in man and similar potentiation might be expected in animals.

The concurrent use of sedative or analgesic drugs is likely to reduce the level of isoflurane required to induce and maintain anaesthesia.

In horses, detomidine and xylazine have been reported to reduce MAC for isoflurane.

In dogs, morphine, oxymorphone, acepromazine, medetomidine plus midazolam have been reported to reduce the MAC for isoflurane. The concomitant administration of midazolam/ketamine during isoflurane anaesthesia may result in marked cardiovascular effects, particularly arterial hypotension. The depressant effects of propranolol on myocardial contractility are reduced during isoflurane anaesthesia, indicating a moderate degree of β -receptor activity.

In cats, intravenous administration of midazolam-butorphanol has been reported to alter several cardio-respiratory parameters in isoflurane-induced cats as has epidural fentanyl and medetomidine. Isoflurane has been shown to reduce the sensitivity of the heart to adrenaline (epinephrine).

In cockatoos, butorphanol has been reported to reduce the MAC for isoflurane.

In pigeons, midazolam has been reported to reduce the MAC for isoflurane.

For reptiles and small mammals, there are no data available.

Isoflurane has a weaker sensitising action on the myocardium, to the effects of circulating dysrhythmogenic catecholamines, than halothane.

Isoflurane may be degraded to carbon monoxide by dried carbon dioxide absorbents.

Overdose

Isoflurane overdose may result in profound respiratory depression. Therefore, respiration must be monitored closely and supported when necessary with supplementary oxygen and/ or assisted ventilation.

In cases of severe cardiopulmonary depression, administration of isoflurane should be discontinued, the breathing circuit should be flushed with oxygen, the existence of a patent airway ensured, and assisted or controlled ventilation with pure oxygen initiated.

Cardiovascular depression should be treated with plasma expanders, pressor agents, antiarrhythmic agents or other appropriate techniques.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Cardboard box containing 100 ml or 250 ml amber coloured glass bottles (Type III) with low density polyethylene-lined caps.

Not all pack sizes may be marketed.