

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ISOFLURIN 1000 mg/g Inhalation Vapour, Liquid
Isoflurane

2. STATEMENT OF ACTIVE SUBSTANCES

Isoflurane 1000 mg/g

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. INDICATIONS

[To be included only for medicinal products not subject to medical prescription.]

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Horse: Meat and offal: 2 days

Not authorised for use in mares producing milk for human consumption.

9. SPECIAL WARNINGS, IF NECESSARY

Anaesthetics must be handled correctly. See package leaflet for user warnings.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Store in the original container.

Protect from light.

Keep the bottle tightly closed.

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

Disposal: read package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetpharma Animal Health, S.L.
Les Corts, 23
08028 Barcelona
Spain

16. MARKETING AUTHORISATION NUMBER

Vm 32509/4031

17. MANUFACTURER'S BATCH NUMBER
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Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{IMMEDIATE PACKAGE: 100 and 250 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ISOFLURIN 1000 mg/g Inhalation Vapour, Liquid
Isoflurane

2. STATEMENT OF ACTIVE SUBSTANCES

Isoflurane 1000 mg/g

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. INDICATIONS

[To be included only for medicinal products not subject to medical prescription.]

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

Horse: Meat and offal: 2 days

Not authorised for use in mares producing milk for human consumption.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Store in the original container.

Protect from light.

Keep the bottle tightly closed.

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

[Not required on the immediate label.]

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

For animal treatment only. To be supplied only on veterinary prescription.

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

[Not required on the immediate label.]

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetpharma Animal Health, S.L.

Les Corts, 23

08028 Barcelona

Spain

16. MARKETING AUTHORISATION NUMBER

Vm 32509/4031

17. MANUFACTURER'S BATCH NUMBER
--

Lot {number}

PACKAGE LEAFLET

ISOFLURIN 1000 mg/g Inhalation Vapour, Liquid

Isoflurane

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

Marketing authorisation holder:

Vetpharma Animal Health, S.L.
Les Corts, 23
08028 Barcelona
Spain

Manufacturer responsible for batch release:

CHEMICAL IBÉRICA PV, S.L.
Ctra. Burgos-Portugal, Km. 256
Calzada de Don Diego, 37448 Salamanca
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ISOFLURIN 1000 mg/g Inhalation Vapour, Liquid

Isoflurane

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each g contains:

Active substance:

Isoflurane1000 mg

Clear, colourless, mobile, heavy liquid.

4. INDICATIONS

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/ halogenated inhalation anaesthetics.

6. ADVERSE REACTIONS

Isoflurane produces hypotension and respiratory depression in a dose-related manner. Cardiac arrhythmias and transient bradycardia have been reported rarely. Malignant hyperthermia has been reported very rarely in susceptible animals.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

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

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

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

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

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. The use of analgesia for painful procedures is consistent with good veterinary practice.

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

Although anaesthetics have a low potential for damage to the atmosphere, it is good practice to use charcoal filters with scavenging equipment, rather than to discharge them into the air.

HORSE

The MAC for isoflurane in the horse is approximately 13.1 mg/g.

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, alfentanil, atracurium, butorphanol, detomidine, diazepam, dobutamine, dopamine, guiaphenesin, ketamine, morphine, pentazocine, 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

Detomidine and xylazine have been reported to reduce the MAC for isoflurane in horses.

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 guiaphenesin. Concentrations of 30 to 50 mg/g isoflurane may then be used to achieve the desired depth of anaesthesia in 5 to 10 minutes.

Isoflurane at a concentration of 30 to 50 mg/g in a high flow oxygen may be used for induction in foals.

Maintenance

Anaesthesia may be maintained using 15 to 25 mg/g isoflurane.

Recovery

Recovery is usually smooth and rapid.

DOG

The MAC for isoflurane in the dog is approximately 12.8 mg/g.

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, etomidate, 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

Morphine, oxymorphone, acepromazine, medetomidine, medetomidine plus midazolam have been reported to reduce the MAC for isoflurane in dogs.

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.

Induction

Induction is possible by face mask using up to 50 mg/g isoflurane, with or without premedication.

Maintenance

Anaesthesia may be maintained using 15 to 25 mg/g isoflurane.

Recovery

Recovery is usually smooth and rapid.

CAT

The MAC for isoflurane in the cat is approximately 16.3 mg/g.

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, atracurium, 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

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).

Induction

Induction is possible by face mask using up to 40 mg/g isoflurane, with or without premedication.

Maintenance

Anaesthesia may be maintained using 15 to 30 mg/g isoflurane.

Recovery

Recovery is usually smooth and rapid.

ORNAMENTAL BIRDS

Few MAC/ED₅₀ values have been recorded. Examples are 13.4 mg/g for the Sandhill crane, 14.5 mg/g for the racing pigeon, reduced to 8.9 mg/g by the administration of midazolam, and 14.4 mg/g for cockatoos, reduced to 10.8 mg/g 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

Butorphanol has been reported to reduce the MAC for isoflurane in cockatoos. Midazolam has been reported to reduce the MAC for isoflurane in pigeons.

Induction

Induction with 30 to 50 mg/g 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, 20 to 30 mg/g is suitable and safe.

Only 6 to 10 mg/g may be needed for some stork and heron species.

Up to 40 to 50 mg/g may be needed for some vultures and eagles.

35 to 40 mg/g 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

Isoflurane is considered by several authors to be the anaesthetic of choice for many species. The literature records its 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 31.4 mg/g at 35°C and 28.3 mg/g at 20°C.

Drug interactions/ compatibilities

No specific publications on reptiles have reviewed compatibilities or interactions of other drugs with isoflurane anaesthesia.

Induction

Induction is usually rapid at 20 to 40 mg/g isoflurane.

Maintenance

10 to 30 mg/g is a useful concentration

Recovery

Recovery is usually smooth and rapid

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

Isoflurane has been recommended for anaesthesia of a wide variety of small mammals.

The MAC for mice has been cited as 13.4 mg/g, and for the rat as 13.8 mg/g, 14.6 mg/g and 24 mg/g.

Drug interactions/ compatibilities

No specific publications on small mammals have reviewed compatibilities or interactions of other drugs with isoflurane anaesthesia.

Induction

Isoflurane concentration 20 to 30 mg/g.

Maintenance

Isoflurane concentration 2.5 to 20 mg/g.

Recovery

Recovery is usually smooth and rapid.

Guide to induction and maintenance of anaesthesia by species

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, hamsters, chinchillas, gerbils, guinea pigs and ferrets	1.34 (mouse) 1.38/1.46/2.40 (rat)	2.0 – 3.0	0.25 – 2.0	Smooth and rapid

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.

10. WITHDRAWAL PERIOD

Horse: Meat and offal: 2 days

Not authorised for use in 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.

Store in the original container.
Protect from light.
Keep the bottle tightly closed.

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

12. SPECIAL WARNINGS

Special warnings for each target species:

The ease and rapidity of alteration of the depth of anaesthesia with isoflurane and its low metabolism, may be considered advantageous for its use in special groups of patients such as the old or young, and those with impaired hepatic, renal or cardiac function.

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 the 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 is important to monitor breathing and pulse for the frequency and its features. Respiratory arrest should be treated by assisted ventilation.

It is important to maintain airways free and properly oxygenate tissues during the maintenance of anaesthesia. In the case of cardiac arrest, perform a complete cardio pulmonary resuscitation.

The metabolism of isoflurane in birds and small mammals, can be affected by decreases in body temperature, that may occur secondary to a high surface area to body weight ratio. Therefore, body temperature should be monitored and kept stable during treatment.

Drug metabolism in reptiles is slow and highly dependent upon environmental temperature. Reptiles may be difficult to induce with inhalation agents due to breath holding.

Like other inhalation anaesthetics of this type, isoflurane depresses the respiratory and cardiovascular systems.

When using isoflurane to anaesthetise an animal with a head injury, consideration should be given as to whether artificial ventilation is appropriate to help avoid increased cerebral blood flow by maintaining normal CO₂ levels.

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

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.

Exposure to anaesthetics can harm the unborn child. 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 the 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 the 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.

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.

Interaction with other medicinal products and other forms of interaction:

The action of muscle relaxants in man, especially those of the nondepolarising (competitive) type such as atracurium, pancuronium or vecuronium, is enhanced by isoflurane. Similar potentiation might be expected to occur in the target species, although there is little direct evidence to this effect. 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 produce and maintain anaesthesia. Some examples are given in section 8.

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 (symptoms, emergency procedures, antidotes):

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.

Incompatibilities:

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.

Other precautions:

Although anaesthetics have a low potential for damage to the atmosphere, it is good practice to use charcoal filters with scavenging equipment, rather than to discharge them into the air.

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes: 100 ml and 250 ml.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 20 November 2020

