SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Iso-Vet 1000 mg/g Inhalation Vapour, liquid

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:
Isoflurane 1000 mg/g
The veterinary medicinal product contains no excipients.

3. PHARMACEUTICAL FORM

Inhalation vapour, Liquid.
Clear, colourless, mobile, heavy liquid

4. CLINICAL PARTICULARS

4.1 Target Species

Horses, dogs, cats, ornamental birds, reptiles, rats, mice, hamsters, chinchillas, gerbils, guinea pigs, ferrets and piglets (up to 7 days of age).

4.2 Indications for use, specifying the target species

Horses, dogs, cats, ornamental birds, reptiles, rats, mice, hamsters, chinchillas, gerbils, guinea pigs and ferrets: Induction and maintenance of general anaesthesia

Piglets (up to 7 days of age):
For general anaesthesia during the castration of male piglets in combination with the preoperative parenteral administration of a suitable analgesic to relieve postoperative pain.

4.3 Contraindications

Do not use in cases of known susceptibility to malignant hyperthermia.
Do not use in cases of known hypersensitivity to isoflurane.

4.4 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.

Piglets (up to 7 days of age):
When using a system which does not allow individual adjustment of the delivered dosage to each piglet, attention should be paid to the homogeneity of the group of animals to be anaesthetized simultaneously, in terms of age and weight. Care must be taken to ensure that the anaesthetic mask fits securely and tightly in order to guarantee a sufficient depth of anaesthesia for each individual animal.

To ensure safe and reliable anaesthesia, the sufficient depth of anaesthesia should be verified by appropriate reflex testing in each individual animal before the start of a painful procedure.

The use of a multimodal perioperative pain management is recommended.

4.5 Special precautions for use

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 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 cardiopulmonary 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 CO_2 levels.

Piglets (up to 7 days of age):

Piglets should be observed for a sufficiently long time after castration in order to be able to recognise and, if necessary, treat post-operative bleeding.

Care must be taken to ensure that the piglets do not cool down and, when awake, are returned to the mother sow as soon as possible.

Do not use in piglets with anatomical anomalies in the genital area (e.g. cryptorchidism).

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

Isoflurane induces anaesthesia in humans. Moreover, it may induce liver damage and also allergic reactions to isoflurane have been reported. Fatigue, headache, or reduced reaction times have been reported at exposures below therapeutic doses. Splashes to the eye may induce irritation.

Do not breathe the vapour. Wash any splashes from skin and eyes, 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.

Contaminated work clothing should be taken off and washed before reuse.

Operating rooms and recovery areas should be provided with adequate ventilation or scavenging systems to prevent the accumulation of anaesthetic vapour. 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 isoflurane odour or adverse health effects such as dizziness etc remove from the source of exposure and go to fresh air. In case of severe accidental exposure seek urgent medical assistance and show this label.

Isoflurane passes the placenta and transfers from maternal to foetal blood. Adverse effects on foetuses and pregnant animals were observed in laboratory animals. Pregnant and/or breast- feeding women should not have any contact with the product and should avoid operating rooms and animal recovery areas.

Adverse effects on male fertility cannot be excluded. In male rats, effects on fertility parameters were observed after repeated exposure at higher concentrations. Prevent inhalation exposure to high concentrations by carefully following the instructions in the product information.

Piglets (up to 7 days of age)

In order to ensure that the safety of the workplace is maintained, castration may only be carried out using an appropriate inhalation device equipped with scavenging double masks.

The exposure of the user should be kept as low as possible. Operating theatres and recovery areas should be equipped with adequate ventilation to prevent accumulation of isoflurane vapours in the air breathed. In the case of underfloor ventilation, artificial ventilation must be set.

When the anaesthetic gas is used in a pig holding, a suitable isoflurane filling device should be used. Isoflurane tanks should preferably be filled outdoors, but at least in very well- ventilated rooms outside the rooms where animals are kept, with as few staff in the room as possible. It is recommended that the filling of isoflurane is monitored by additional personnel not involved in the filling process in case of an accidental exposure event.

Vaporizers should be switched off when not in use. It is advisable to have an isoflurane container with a capacity adapted to the amount needed for a whole day, so that the container does not need to be filled during anaesthesia.

It must be ensured that the mask used seals tightly for each individual piglet in order to avoid additional exposure of the workplace**.** Free escape from an unoccupied anaesthesia mask (no piglets in anaesthesia mask) must be prevented.

To the physician: Ensure a patient airway is clear and give symptomatic and supportive treatment. Note that adrenaline and catecholamines may cause cardiac arrhythmias.'

4.5 iii) Other Precautions: Isoflurane is a gas with a global-warming potential and ozone depletion potential; thus it is good practice to use charcoal filters with scavenging equipment, rather than to discharge the gas into the air.

4.6 Adverse reactions (frequency and seriousness)

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.

Isoflurane may produce excitations (tremors, restlessness), pale mucous membranes and prolonged recovery time

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- 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).

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Use only accordingly 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 accordingly to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

The action of muscle relaxants in man, especially those of the nondepolarizing (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. For example, opiates, alpha-2-agonists, acepromazine, and benzodiazepines have been reported to reduce the MAC values.

The same was reported with the simultaneous use of non-steroidal anti-inflammatory drugs in the castration of piglets.

Some examples are given in 4.9.

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.

4.9 Amounts to be administered and administration route

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 ED_{50} 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.

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, alfentanil, atracurium, butorphanol, detomidine, diazepam, dobutamine, dopamine, guaiphenesin, 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 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, 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 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, 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 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/ED_{50} 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

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 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

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 ED_{50} was determined in the desert iguana to be 3.14% at 35˚C and 2.83% 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 2 to 4% isoflurane.

Maintenance

1 to 3% 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 1.34%, and for the rat as 1.38%, 1.46% and 2.4%.

Drug interactions/ compatibilities

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

Induction

Isoflurane concentration 2 to 3%.

Maintenance

Isoflurane concentration 0.25 to 2%.

Recovery

Recovery is usually smooth and rapid.

PIGS (CASTRATION OF PIGLETS UP TO 7 DAYS OF AGE):

For piglets (up to 7 days of age)

Isoflurane concentration of up to 5Vol%, with oxygen as carrier gas with a flow rate of 2L/min.

The MAC value for isoflurane in pigs is 1.41-2.00%.

Premedication:

Post-operative pain must be controlled by the timely parenteral administration of appropriate analgesics before the induction of anaesthesia.

Induction:

Isoflurane concentrations of up to 5 Vol % are used for the anaesthetic induction (with oxygen as carrier gas with a flow rate of 2L/min). After 70-90 seconds a sufficient depth of anaesthesia is generally achieved. The actual duration required in practice depends on many variables. It is therefore imperative that the depth of anaesthesia be clinically checked by means of reflexes in each individual animal before castration is started. The inter- and dew claw reflexes are particularly suitable.

The castration may only be carried out under controlled supply of isoflurane, using a suitable inhalation device tested for the purpose. For the individual animal, it must be ensured that the mask used is leak-proof and that the exhaust air is filtered and discharged into a room
(e.g. outdoors) where a sufficient rate of air exchange is achieved.

The product should only be used for uncomplicated castration procedures that are anticipated to be short in duration (maximum of 120 seconds for the entire procedure from the induction of anaesthesia to the end of castration of a piglet).

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, 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
Pigs (piglets up to 7 days of age)	1.41-2.00	Up to 5.0	-	Smooth and rapid

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

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.

4.11 Withdrawal period(s)

Horses:
Meat and offal: 2 days
Not authorised for use in mares producing milk for human consumption.

Pigs (piglets up to 7 days of age):
Meat and offal: 2 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anaesthetic, general - halogenated hydrocarbons
ATCvet code: QN01AB06

5.1 Pharmacodynamic properties

Isoflurane produces unconsciousness by its action on the central nervous system. It has little or no analgesic properties.

Like other inhalation anaesthetics of this type, isoflurane depresses the respiratory and cardiovascular systems.
Isoflurane is absorbed on inhalation and is rapidly distributed via the bloodstream to other tissues, including the brain.
Its blood/gas partition coefficient at 37°C is 1.4. The absorption and distribution of isoflurane and the elimination of non-metabolised isoflurane by the lungs are all rapid, with the clinical consequences of rapid induction and recovery and easy and rapid control of the depth of anaesthesia.

5.2 Pharmacokinetic particulars

Metabolism of isoflurane is minimal (about 0.2%, mainly to inorganic fluoride) and almost all of the administered isoflurane is excreted unchanged by the lungs.

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 formation of carbon monoxide in rebreathing circuits and the possibility of elevated carboxyhaemoglobin levels, carbon dioxide absorbents should not be allowed to dry out.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Type III amber glass bottles containing 100 ml or 250 ml of isoflurane, fitted with a black phenolic urea /polypropylene screw cap with a low-density polyethylene cone insert.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 51310/5000

9. DATE OF FIRST AUTHORISATION

12 August 2009

10. DATE OF REVISION OF THE TEXT

December 2025

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be supplied only on veterinary prescription
Not to be sold to animal owners.

Gavin Hall
Approved: 05 December 2025