

SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

IsoFlo Vet 100% w/w Inhalation Vapour, liquid

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

IsoFlurane

Each millilitre contains 100% w/w isoflurane

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Inhalation vapour, liquid

A clear, colourless volatile liquid with a mildly pungent odour.

4. CLINICAL PARTICULARS

4.1 Target species

Rabbits.

4.2 Indications for use, specifying the target species

Induction and maintenance of general anaesthesia.

4.3 Contraindications

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

Do not use in case of hypersensitivity to isoflurane.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

i. Special precautions for use in animals

The use of the product in cardiopathic patients 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. Respiratory arrest should be treated by assisted ventilation. It's 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.

ii. Special precautions for 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.

Pregnant and breast-feeding women should not have any contact with the product and should avoid operating 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 Isoflurane 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.

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 only rarely.

Malignant hyperthermia has been reported very rarely in susceptible animals.

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.

4.7 Use during pregnancy, lactation or lay

Pregnancy:

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

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 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 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 absorbents.

4.9 Amount(s) 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 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. 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 discharge them into the air.

RABBIT

The MAC for the rabbit has been cited as 2.05%.

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.

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)

This product is not intended for use in rabbits intended for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anaesthetic, general – halogenated hydrocarbons

ATC Vet Code: QN01AB06

5.1 Pharmacodynamic properties

Isoflurane produces unconsciousness by its action on the central nervous system and is a good muscle relaxant for surgical purposes. It has little or no analgesic properties.

Like other inhalational anaesthetics of its 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 properties

Metabolism of isoflurane is minimal (about 0.2%, mainly to organic 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 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.
Store in tightly closed original container.
Protect from direct sunlight
Protect from direct heat

6.5 Nature and composition of immediate packaging

Amber coloured glass bottle (Type III) containing 100ml or 250ml isoflurane. The bottle has an aluminium roll-on pilfer-proof cap with polyethylene liner and a low density polyethylene neck collar with wing ("keyed" collar) which is

fitted over the cap and bottle neck.
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, 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

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4196

9. DATE OF FIRST AUTHORISATION

23 October 1996

10. DATE OF REVISION OF THE TEXT

July 2015

APPROVED *T. NASH* 27/07/15