PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

IsoFlo Vet 100% w/w Inhalation Vapour, liquid

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 100% w/w Isoflurane

3. PHARMACEUTICAL FORM

Inhalation vapour, liquid

4. PACKAGE SIZE

250ml

100ml

Not all pack sizes may be marketed

5. TARGET SPECIES

For use in rabbits

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

It is not intended for use in rabbits intended for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

Operator Warnings: Important to read the package leaflet before handling and administering the product

10. EXPIRY DATE

EXP {month/year}

Do not use after stated expiry date

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

Store in tightly closed original container

Protect from direct sunlight

Protect from direct heat

Keep the container in the outer carton.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waster regulation authority

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-V

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 reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4196

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

IsoFlo Vet 100% w/w Inhalation Vapour, liquid

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 100% w/w Isoflurane

3. PHARMACEUTICAL FORM

Inhalation vapour, liquid

4. PACKAGE SIZE

250ml

100ml

Not all pack sizes may be marketed

5. TARGET SPECIES

For use in rabbits

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

It is not intended for use in rabbits intended for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

Operator Warnings: Important to read the package leaflet before handling and administering the product

10. EXPIRY DATE

EXP {month/year}

Do not use after stated expiry date

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C

Store in tightly closed original container

Protect from direct sunlight

Protect from direct heat

Keep the container in the outer carton.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waster regulation authority

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-V

For animal treatment only – to be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

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15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4196

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PACKAGE LEAFLET FOR:

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

Marketing Authorisation Holder

Zoetis UK Limited

5th Floor, St Andrew Street

London

EC4A 3AE

Manufacturer for the batch release

Aesica Queenborough Ltd

Queenborough

Kent

ME11 5EL

United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

IsoFlo Vet 100% w/w Inhalation Vapour, liquid

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

A clear, colourless volatile liquid for the generation of gaseous anaesthetic, with a mildly pungent odour, containing 100% w/w isoflurane

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 case of hypersensitivity to isoflurane

6. ADVERSE REACTIONS

Isoflurane produces hypotension and respiratory depression in a dose-related manner. It is important that respiration and pulse should be monitored for both rate and character.

Respiratory arrest should be treated by assisted ventilation with air or, preferably, with oxygen supplementation. It is important that a patent airway be maintained and adequate tissue oxygenation achieved throughout the period of anaesthesia. Should cardiac arrest occur, full cardiopulmonary resuscitation methods should be applied. Cardiac arrhythmias and transient bradycardia have been reported only rarely. However, isoflurane has a weaker sensitising action on the myocardium, to the effects of dysrhythmogenic circulating catecholamines, than halothane.

Malignant hyperthermia has been reported very rarely in susceptible animals.

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

7. TARGET SPECIES

Rabbits

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

Premedication:

Isoflurane may be used with other drugs commonly used in veterinary anaesthetic regimes. Drugs used for premedication should be selected for the individual patient. See Contra-indications, warnings etc for potential drug interactions.

The MAC (minimal aveolar concentration) in oxygen is given below for the target species and should be used as a guide only. The actual concentration required in practice will depend on many variables including the concomitant use of other drugs and the clinical status of the patient.

Induction, Maintenance and Recovery: See table below:

Species	MAC (%)	Induction (%)*	Maintenance (%)
Rabbit	2.05	2.0-3.0%	0.25-2.0%

*Induction usually occurs via a face mask

Recovery is normally smooth and rapid

Species specific interactions:

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

9. ADVICE ON CORRECT ADMINISTRATION

IsoFlo Vet should be used only in an isoflurane specific vaporiser.

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/nitrous oxide mixtures.

10. WITHDRAWAL PERIOD(S)

It is not intended for use in rabbits intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children

Do no store above 25°C. Store in tightly closed original container. Protect from direct sunlight.

Protect from direct heat. Keep container in outer carton.

Do not use after the expiry date which is stated on the label and carton after EXP.

12. SPECIAL WARNING(S)

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 CO_2 levels, so that cerebral blood flow does not increase.

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 or renal function, or cardiac function.

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.

The action of muscle relaxants in man, especially those of the non-depolarising type such as atracuruim, pancuronium or vacuronimum 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 concomitant administration of midazolam/ketamine during isoflurane anaesthesia mat result in marked cardiovascular effects, particularly arterial hypotension.

Use in pregnant and lactating animals should be limited to cases in which the benefits outweigh the risks.

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.

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 try out.

OPERATOR WARNINGS:

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 isoflurane 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.

Used cuffed endotracheal intubation when possible for the administration of Isoflo 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 anaesthetics 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.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.

Isoflurane produces unconsciousness by its action on the central nervous system. It has little or no analgesic properties and consideration should be given to the analgesic requirements of the patient before the termination of general anaesthesia. The use of analgesia for painful procedures is consistent with good veterinary practice.

To be supplied only on veterinary prescription.

For Animal Treatment Only

Package quantities: 100ml and 250ml bottle

Not all pack sizes may be marketed

Marketing Authorisation number Vm 42058/4196

POM-V

Distributed by:

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