PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGE {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Isofane 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

100ml or 250ml

5. TARGET SPECIES

Horses, dogs, cats, small mammals, ornamental birds and reptiles

6. INDICATION(S)

To induce and maintain anaesthesia in all types of veterinary surgery

7. METHOD AND ROUTE(S) OF ADMINISTRATION

See package leaflet for details of dosing

8. WITHDRAWAL PERIOD

Not to be used in animals intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in animals sensitive to isoflurane or other halogenated or inhalation anaesthetic agents. Do not use in animals with a known susceptibility to malignant hyperthermia.

Isofane should only be used in an accurately calibrated isoflurane specific vaporiser. Heart rate usually remains stable with isoflurane, however both respiration and blood pressure are depressed in a dose-related manner. Pulse and respiration should be assessed for both rate and character in all patients.

Consideration should be given to supplemental ventilation, especially in animals which have sustained injuries which may lead to increased CO2 levels or a depressed heart rate. In animals with head injuries consider supplemental ventilation to maintain normal circulating CO2 levels such that cerebral blood flow does not increase. Blood pressure should be assessed throughout anaesthesia. Hypotension, if related to depth of anaesthesia, can be corrected by a reduction in delivered isoflurane concentration. In horses, as with all anaesthetic agents, it may sometimes be necessary to administer an ionotropic agent in hypotension. Isoflurane appears to sensitise the myocardium to the dysrhythmogenic effects of circulating catecholamines to a lesser extent than halothane.

Muscle relaxation with isoflurane is normally adequate for the majority of surgical procedures. If a more profound muscle relaxation is required, e.g. for thoracic surgery, additional muscle relaxants may be employed. All commonly available non-depolarising muscle relaxants are potentiated by isoflurane and the effects will be maintained for longer than is usual with these agents. In dogs, care should be taken if administering a midazolam-ketamine combination to an animal already anaesthetised with isoflurane.

Isoflurane causes dose related respiratory and cardiovascular depression. It is important that both respiration and cardiovascular function is monitored for both rate and character. Respiratory arrest should be treated by assisted ventilation, preferably with oxygen supplementation. Maintain a patent airway and adequate tissue oxygenation throughout the period of anaesthesia.

Horses: Recovery from isoflurane anaesthesia is generally smooth and rapid. However, one report suggests that horses recovering from isoflurane anaesthesia may appear un-coordinated. It is important to provide adequate post-anaesthetic analgesia since isoflurane anaesthetised horses may become aware of their surroundings more rapidly than horses recovering from halothane anaesthesia. Isoflurane has been reported to interact with dry carbon dioxide absorbents to form carbon monoxide. In order to minimise the risk of this in rebreathing circuits, and the possibility of elevated carboxyhaemaglobin levels, absorbents should not be allowed to dry out.

Operator warnings:
Do not breathe the vapour. The Occupational Exposure Standard (OES) for isoflurane has been set at 50 ppm on an 8-hour weighted average.
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.
To protect the environment it is considered good practice to use charcoal filters with scavenging/ventilation equipment.

Avoid using masking procedures for prolonged induction and maintenance of general anaesthesia. Use cuffed endotracheal intubation when possible for the administration of Isofane during maintenance of general anaesthesia.
Care should be taken when dispensing isoflurane, with any spillage removed immediately using an inert and absorbent material e.g. sawdust.

Pregnant and breast-feeding women should avoid exposure to the product and should avoid operating rooms and animal recovery areas.
Wash any splashes from skin and eyes immediately and avoid contact with the mouth.
In the event of severe accidental exposure; remove the operator from the source of the exposure and seek urgent medical assistance and show this label.
Halogenated anaesthetic agents may induce liver damage. In the case of isoflurane this is an idiosyncratic response very rarely seen after repeated exposure.

Advice to doctors: maintain a patent airway and give symptomatic and supportive treatment. Note that adrenaline and catecholamines may cause cardiac dysrhythmias.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Keep the container tightly closed.
Protect from light.
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 waste 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 SIGHT AND REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Piramal Critical Care Limited
Suite 4, Ground Floor
Heathrow Boulevard - East Wing
280 Bath Road
West Drayton
UB7 0DQ
United Kingdom

Distributed by:

AH UK Animal Health (PVT) Ltd
College Mains Road
Dumfries
DG2 ONU
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 37071/4001

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS
{Bottle Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Isofane 100% w/w Inhalation vapour, liquid.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Contains: 100% w/w isoflurane

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

100 or 250 ml

4. ROUTE(S) OF ADMINISTRATION

Inhalation vapour
To induce and maintain anaesthesia in all types of veterinary surgery. For use in Horses, dogs, cats, small mammals, ornamental birds and reptiles.
See enclosed leaflet for directions for use and operator warnings.

5. WITHDRAWAL PERIOD

Not to be used in animals intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
IMPORTANT
Read instructions before use.
Keep the container in the outer carton. Do not store above 25^{o}C. Keep container tightly closed. Protect form light
Keep out of sight and reach of children.
POM – V To be supplied only on veterinary prescription
Vm 37071/4001

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Suite 4, Ground Floor
Heathrow Boulevard - East Wing
280 Bath Road
West Drayton
UB7 0DQ
United Kingdom

Distributed by:
AH UK Animal Health (PVT) Ltd
College Mains Road
Dumfries
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United Kingdom

PACKAGE LEAFLET FOR:

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

Marketing authorisation holder and manufacturer responsible for batch release:

Piramal Critical Care Limited
Suite 4, Ground Floor
Heathrow Boulevard - East Wing
280 Bath Road
West Drayton
UB7 0DQ
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Isofane 100% *w/w* Inhalation vapour, liquid.

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

A volatile, clear, non-flammable liquid containing 100% w/w isoflurane (1-Chloro-2,2,2-trifluoroethyl difluoromethyl ether) for generation of gaseous anaesthesia.

4. INDICATION(S)

To induce and maintain anaesthesia in all types of veterinary surgery in horses, dogs, cats, small mammals, ornamental birds and reptiles.

5. CONTRAINDICATIONS

Do not use in animals sensitive to isoflurane or other halogenated or inhalation anaesthetic agents. Do not use in animals with a known susceptibility to malignant hyperthermia.

6. ADVERSE REACTIONS

Heart rate usually remains stable with isoflurane, however both respiration and blood pressure are depressed in a dose-related manner. Pulse and respiration should be assessed for both rate and character in all patients.

Consideration should be given to supplemental ventilation, especially in animals which have sustained injuries which may lead to increased CO2 levels or a depressed heart rate. In animals with head injuries consider supplemental ventilation to maintain normal circulating CO2 levels such that cerebral blood flow does not increase. Blood pressure should be assessed throughout anaesthesia. Hypotension, if related to depth of anaesthesia, can be corrected by a reduction in delivered isoflurane concentration. In horses, as with all anaesthetic agents, it may sometimes be necessary to administer an ionotropic agent in hypotension. Isoflurane appears to

sensitise the myocardium to the dysrhythmogenic effects of circulating catecholamines to a lesser extent than halothane.

7. TARGET SPECIES

Horses, dogs, cats, small mammals, ornamental birds and reptiles

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

Pre-medication: The pre-medication should be chosen according to the type and condition of the animal and the surgical procedure planned. Isoflurane has been shown to be compatible with the most commonly used veterinary premedicant agents. The use of sedative or analgesic drugs is likely to reduce the concentration of isoflurane required to induce or maintain anaesthesia.
Induction: The dose for induction of anaesthesia will vary according to species, but is generally between 2% and 5% concentration in an oxygen, or oxygen/nitrous oxide mixture. The table below presents a guide to the concentrations required for induction of anaesthesia by species based on use of Isofane with oxygen. When used in conjunction with oxygen/nitrous oxide a lower concentration of isoflurane may be required. Speed of induction and the concentration of isoflurane required may vary according to several different influences, including the health and medication status of the patient.
Observation of effect and clinical judgement will be required to determine the most appropriate induction dose in each case.
Maintenance: A guide to maintenance dose by species based on use of the product with oxygen is presented in the table below. When used in conjunction with oxygen/nitrous oxide a lower concentration of isoflurane may be required. The specific dose required may vary according to several different influences, including the health and medication status of the patient.
Clinical judgement will be required to determine the most appropriate dose in each case.
Recovery: Recovery from anaesthesia is generally rapid, uneventful and smooth.

Guide to induction and maintenance of anaesthesia by species
(Isofane concentration in oxygen)

Species	**Induction (%)**	**Maintenance (%)**	**MAC* (%)**
Horse	3.0 – 5.0 (Foals)	1.5 – 2.5	1.31
Dog	Up to 5.0	1.5 – 2.5	1.3
Cat	Up to 4.0	1.5 – 3.0	1.61
Ornamental birds	Up to 5.0	2.0 – 3.0	1.5
Reptiles	2.0 - 4.0	1.0 – 3.0	N/a
Small Mammals	2.0 – 3.0	0.25 – 2.0	Rabbit 2.05 Mouse 1.34 Rat 1.38 – 2.4

* Minimum Alveolar Concentration at which 50% of anaesthetised patients show no response to a stimulus.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

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11. SPECIAL STORAGE PRECAUTIONS

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Advice to doctors*:* maintain 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

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14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2021

15. OTHER INFORMATION

POM – V To be supplied only on veterinary prescription
Vm 37071/4001
Package quantities: 100 or 250ml glass bottle. Not all pack sizes may be marketed.
Further information:
Isoflurane is very poorly metabolised (estimated 0.2%) with the majority being eliminated unchanged via the lungs. The main metabolites, inorganic fluoride and trifluoroacetic acid are excreted by the kidneys and eliminated in the urine.
Isoflurane has been successfully used in pregnant animals, including the horse, dog and cat, for Caesarean section. Reproduction studies in mice, rats and rabbits show no evidence of effect on foetal malformation specifically attributable to isoflurane at clinically relevant doses. However, specific studies in the target species to show the effect on pregnant, lactating or breeding animals have not been undertaken.

Distributor:
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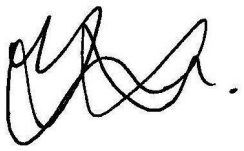
United Kingdom



Approved: 21 April 2021