ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

CARTON TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inductofol 10 mg/ml Emulsion for Injection for Cats and Dogs

10mg propofol/ml

Injectable Anaesthetic

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains: 10 mg propofol

3. PHARMACEUTICAL FORM

Emulsion for Injection

4. PACKAGE SIZE

20ml/50ml

5. TARGET SPECIES

Cats and Dogs

6. INDICATION(S)

The veterinary medicinal product is a short-acting, intravenous general anaesthetic for procedures of short duration, lasting up to 5 minutes:
For induction and maintenance of general anaesthesia using incremental doses to effect.
For induction of general anaesthesia where maintenance is provided by inhalation anaesthetics.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous administration to cats and dogs. Prior to use, the product should be inspected visually for absence of visible droplets or extraneous foreign particles and discarded if present. The vial should be shaken gently but thoroughly before opening. The product should not be mixed with other products.

For dosage, and further information on method and route of administration and special warnings, read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not Applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet.

This is a potent drug: particular care should be taken to avoid accidental self-injection. Read the package leaflet for full user warnings.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Keep vial in the outer container in order to protect from light.
Do not freeze.
Store vials in the upright position.
Avoid introduction of contamination.
Withdrawn product should be used immediately. Product remaining in the container should be discarded.
Do not use after the expiry date listed on the containers and outer cartons after "EXP".

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

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

FOR ANIMAL TREATMENT ONLY

POM-V

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

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

15. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4274

16. MANUFACTURER'S BATCH NUMBER

BN:

FURTHER INFORMATION:
Read package leaflet before use

17. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Ltd
Station Works
Newry
Co. Down
BT35 6JP

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

20 and 50 ml bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inductofol 10 mg/ml Emulsion for Injection for Cats and Dogs

PROPOFOL

Injectable Anaesthetic

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains: 10 mg propofol

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

1 x 20 ml/5 x 20ml/ 1 x 50 ml/5 x 50ml

4. ROUTE(S) OF ADMINISTRATION

For intravenous use only.

Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Not Applicable

6. BATCH NUMBER

BN:

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

FOR ANIMAL TREATMENT ONLY

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN

9. SPECIAL WARNING(S), IF NECESSARY

This is a potent drug: avoid self-administration. Read package leaflet for full user warnings.

Keep vial in the outer container in order to protect from light.

ManA 2000

10. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Ltd
Station Works
Newry
Co. Down
BT35 6JP

INSERT TEXT

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

Marketing Authorisation Holder:
(EU) Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK) Norbrook Laboratories Ltd
Station Works, Camlough Road
Newry Co. Down, BT35 6JP
Northern Ireland

Manufacturer responsible for batch release:
Norbrook Laboratories Limited
Station Works, Camlough Road
Newry, Co. Down, BT35 6JP
Northern Ireland

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inductofol 10 mg/ml Emulsion for Injection for Cats and Dogs

Propofol

Injectable Anaesthetic

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

The product is a white homogenous emulsion for injection containing 10 mg propofol per ml.

4. INDICATION(S)

The veterinary medicinal prodct is a short-acting, intravenous, general anaesthetic for procedures of short duration, lasting up to 5 minutes:
For induction and maintenance of general anaesthesia using incremental doses to effect.

For induction of general anaesthesia where maintenance is provided by inhalation anaesthetics.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Side-effects during induction, maintenance and recovery (including hypersensitivity reactions) are uncommon. Minimal evidence of excitation has been observed in a small proportion of animals. During the recovery phase, vomiting and evidence of excitation have been observed in a small proportion of animals. In clinical trials in cats, transient apnoea during induction and a paw/face-licking characteristic during recovery have been observed in a small proportion of cases.
If panting is evident before induction, it may continue throughout the subsequent periods of anaesthesia and recovery.
Repeated anaesthesia with propofol in cats may cause oxidative injury and Heinz body production. Recovery may also become prolonged. Limiting repeated anaesthesia to intervals of more than 48 hours will reduce the likelihood.

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

7. TARGET SPECIES

Cats and Dogs.

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

For intravenous administration to cats and dogs. Prior to use, the product should be inspected visually for absence of visible droplets or extraneous foreign particles and discarded if present. The vial should be shaken gently but thoroughly before opening. The product should not be mixed with other products.

Induction: The induction dose is calculated according to bodyweight and may be administered to effect over a period of 10 to 40 seconds. Alternatively, the calculated dose may be given in full as a single bolus over a shorter time interval. The induction dose is reduced by the use of premedicants.

The following dose rates are for guidance and in practice the dose rate should be based on response. The average induction dose for dogs and cats, either unpremedicated or when premedicated with a non alpha-2-agonist tranquilliser such as acepromazine, is as follows:

	Dose rate (mg/kg bodyweight)	*Dose volume (ml/kg bodyweight)*
Dogs		
Unpremedicated	6.5	6.5 ml/10 kg
Premedicated	4.0	4.0 ml/10 kg
Cats		
Unpremedicated	8.0	2.0 ml/2.5 kg
Premedicated	6.0	1.5 ml/2.5 kg

Maintenance: Where anaesthesia is maintained by incremental injections, the dose rate will vary between animals. Incremental doses should be given to effect. Doses of around 1 ml per 4.0 to 8.0 kg bodyweight sustain anaesthesia for periods of up to 5 minutes.

Maintenance by inhalation agents: Where inhalation agents are used to maintain general anaesthesia, clinical experience indicates that there may be a need to use a higher initial concentration of inhalation agent than is normally the case following induction with barbiturate agents such as thiopentone.

Continuous and prolonged exposure (greater than 30 minutes) may lead to slower recovery, particularly in cats

9. ADVICE ON CORRECT ADMINISTRATION

Inadvertent perivascular administration rarely causes local tissue reactions.

10. WITHDRAWAL PERIOD

Not Applicable.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Keep vial in the outer container in order to protect from light.
Do not freeze.
Store vials in the upright position.
Keep out of the reach and sight of children. Avoid introduction of contamination.
Withdrawn product should be used immediately. Product remaining in the container should be discarded.
Do not use after the expiry date listed on the containers and outer cartons after “EXP”.

12. SPECIAL WARNINGS

Special Precautions for Use in Animals:
During induction of anaesthesia, mild hypotension and transient apnoea, similar to effects with other intravenous anaesthetic agents may occur. When using the product, facilities for the maintenance of a patent airway, artificial ventilation facilities and oxygen enrichment should be available.
As with other intravenous anaesthetic agents, caution should be exercised in dogs and cats with cardiac, respiratory, renal or hepatic impairment, or in hypovolaemic or debilitated animals.

The safety of this product in foetuses/neonates and during lactation has not been established, but the product has been used successfully for induction prior to Caesarean section in bitches.
Use only according to the benefit/risk assessment by the responsible veterinarian

The product is a stable emulsion; discard the vial if phase separation is observed. If the product is injected very slowly, an inadequate plane of anaesthesia can occur

The concurrent use of sedative or analgesic drugs is likely to reduce the dose of propofol required to produce and maintain anaesthesia.

The emulsion should not be mixed with other therapeutic agents or infusion fluids prior to administration.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This is a potent drug: particular care should be taken to avoid accidental self-administration. Preferably use a guarded needle until the moment of injection.
Wash off splashes from the skin and eyes immediately.
In the event of accidental self-administration, seek urgent medical attention and show the label to advise the doctor.

Advice to Doctor:
Do not leave patient unattended. Maintain airways and give symptomatic and supportive treatment.

Interaction with other medicinal products and other forms of interaction:
Propofol has been used in association with commonly used premedicants, e.g. atropine, acepromazine, diazepam; inhalational agents, e.g. halothane, nitrous oxide, enflurane; and analgesic agents, e.g. buprenorphine. No pharmacological incompatibility has been encountered.

Overdose (symptoms, emergency procedures, antidotes):
Accidental overdosage is likely to cause cardio-respiratory depression. Respiratory depression should be treated by artificial ventilation with oxygen. Cardiovascular depression requires the use of plasma expanders and pressor agents.

Incompatibilities:
The product should not be mixed with other products.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2019

15. OTHER INFORMATION

ManA 2000

POM-V

PACKAGING QUANTITIES:

20ml and 50ml type I clear glass vials sealed with bromobutyl bungs and aluminium seals.
Available in cartons of 1 x 20ml, 1 x 50ml, 5 x 20ml and 5 x 50ml.
Not all pack sizes may be marketed.

FURTHER INFORMATION:
Propofol is a substituted phenol which, when given by intravenous injection, is a short-acting anaesthetic with a rapid rate of onset. After a single bolus dose, blood level profiles are characterised by a rapid distribution phase and a rapid elimination phase. No accumulation of blood levels has been observed after multiple daily dosing. Urinary excretion is the major route of elimination of metabolites from the body. Propofol has been used in association with commonly used premedicants, e.g. atropine, acepromazine, diazepam; inhalational agents, e.g. halothane, nitrous oxide, enflurane; and analgesic agents, e.g. buprenorphine. No pharmacological incompatibility has been encountered. The emulsion should not be mixed with other therapeutic agents or infusion fluids prior to administration. Inadvertent perivascular administration rarely causes local tissue reactions.

FOR ANIMAL TREATMENT ONLY

Approved: 22 August 2019

D Austin