MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

20 ml **bottle**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norofol 10mg/ml Emulsion for Injection for Cats and Dogs
Propofol

2. QUANTITY OF THE ACTIVE SUBSTANCES

10 mg/ml propofol

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

20 ml

4. ROUTES 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 WARNINGS

This is a potent drug: avoid self administration. Read package leaflet for full user warnings.
For disposal advice refer to package leaflet.

ManA 2000

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

(UK)
Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

Distributed by:
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

DRAFT LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norofol 10mg/ml Emulsion for Injection for Cats and Dogs
Propofol

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

10 mg/ml propofol

3. PHARMACEUTICAL FORM

Emulsion for Injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Cats and Dogs.

6. INDICATIONS

A short-acting, intravenous general anaesthetic for procedures of short duration, lasting up to 5 minutes; for the induction and maintenance of general anaesthesia using incremental doses to effect; for the induction of general anaesthesia where maintenance is provided by inhalation anaesthetics.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not Applicable

9. SPECIAL WARNINGS

Read the package leaflet before use.

10. EXPIRY DATE

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Do not freeze.
Protect from light.
Keep the container in the outer carton.
Store vials in the upright position
This product does not contain an antimicrobial preservative. Any solution remaining in the vial following withdrawal of the required dose should be discarded.

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

Disposal: read package leaflet.

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

FOR ANIMAL TREATMENT ONLY

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

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

(UK)
Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

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Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4275

17. MANUFACTURER'S BATCH NUMBER

BN:

DRAFT CARTON TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norofol 10mg/ml Emulsion for Injection for Cats and Dogs
Propofol

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

Dogs and Cats

6. INDICATIONS

Norofol Injection is indicated for use in dogs and cats as a short-acting, intravenous general anaesthetic for procedures of short duration, lasting up to 5 minutes; for the induction and maintenance of general anaesthesia using incremental doses to effect and for the induction of general anaesthesia where maintenance is provided by inhalation anaesthetics.

7. METHOD AND ROUTES OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not Applicable

9. SPECIAL WARNINGS

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Protect from light.
Do not freeze.
Store vials in the upright position.
Keep the container in outer carton.
Withdrawn product should be used immediately.
This product does not contain an antimicrobial preservative. Any solution remaining in the vial following withdrawal of the required dose should be discarded.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after 'EXP'. The expiry date refers to the last day of the month.

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

Any unused veterinary 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

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

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

(UK)
Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4275

17. MANUFACTURER'S BATCH NUMBER

BN:

FURTHER INFORMATION: Read the package leaflet before use.

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DRAFT LEAFLET 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 Limited
Station Works
Newry
Co. Down, BT35 6JP
Northern Ireland

Manufacturer Responsible for Batch Release:
(EU)
Norbrook Manufacturing Ltd
Rossmore Industrial Estate
Monaghan
Ireland

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norofol 10mg/ml Emulsion for Injection for Cats and Dogs
Propofol

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each ml contains: 10 mg propofol
A white homogeneous emulsion with no appearance of visible droplets or extraneous foreign particles.

4. INDICATIONS

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 that are hypersensitive to the active substance or any of the excipients.

6. ADVERSE REACTIONS

Side-effects during induction, maintenance and recovery are uncommon. Induction is generally smooth, 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. As with other anaesthetic agents, the possibility of respiratory and cardiovascular depression should be considered.
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. Repeated anaesthesia with propofol in cats may cause oxidative injury and Heinz body formation. Recovery rate may also be prolonged. Limiting repeated anaesthesia to intervals of more than 48 hours will reduce the likelihood. In clinical trials in dogs, transient apnoea during induction and maintenance have been observed.
If panting is evident before induction, it may continue throughout the subsequent periods of anaesthesia and recovery.
Inadvertent perivascular administration rarely causes local tissue reactions.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and Cats

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

The product is indicated for intravenous administration to dogs and cats. Shake the vial gently but thoroughly before opening. The product should be inspected visually for the absence of visible droplets or extraneous foreign particles and discarded if present.

Induction: The induction dose is calculated according to bodyweight and may be administered to effect over a period of 10 to 40 seconds. The induction dose is reduced by the use of premedicants.
Where animals have been premedicated with an α-2 agonist such as medetomidine, the dose of propofol (as with any other intravenous anaesthetic agent) should be reduced by up to 85% (e.g. from 6.5 mg/kg for unpremedicated dogs to 1.0 mg/kg for dogs premedicated with an α-2 agonist).
The average induction dose for dogs and cats, either unpremedicated or when premedicated with a non-α-2 agonist tranquilliser such as acepromazine or an α-2 agonist, is as follows. The following dose rates are for guidance only and in practice the actual dose rate should be based on response.

	Dose (mg/kg bodyweight)	**Dose Volume (ml/kg bodyweight)**
Dogs		
Unpremedicated	6.5 mg/kg	0.65 ml/kg
Premedicated		
With non-α-2 agonist	4.0 mg/kg	0.40 ml/kg
With α-2 agonist	1.0 mg/kg	0.10 ml/kg
Cats		
Unpremedicated	8.0 mg/kg	0.8 ml/kg
Premedicated		
With non-α-2 agonist	6.0 mg/kg	0.60 ml/kg
With α-2 agonist	1.2 mg/kg	0.12 ml/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 approximately 1.25 – 2.5mg (0.125 – 0.25ml) per 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 may lead to slower recovery, particularly in cats.

9. ADVICE ON CORRECT ADMINISTRATION

Norofol Injection should not be mixed with other products.

10. WITHDRAWAL PERIOD

Not Applicable.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Protect from light.
Do not freeze.
Store vials in the upright position.
Keep the container in outer carton.
Keep out of the sight and reach of children.
Withdrawn product should be used immediately.
This product does not contain an antimicrobial preservative. Any solution remaining in the vial following withdrawal of the required dose should be discarded.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after 'EXP'. The expiry date refers to the last day of the month.

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.
If the product is injected too rapidly, cardiopulmonary depression may occur (apnoea, bradycardia, hypotension).
When using Norofol Injection, 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.
Sighthounds may have a slightly longer duration of recovery from anaesthesia compared to other breeds of dog.
Use aseptic techniques when administering the product as it does not contain an antimicrobial preservative.

Special Warnings for each Target Species:
If Norofol is injected very slowly, an inadequate plane of anaesthesia can occur.
Shake the vial gently but thoroughly before opening. Do not use if evidence of phase separation remains after gentle shaking.

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; inhalation agents, e.g. halothane, nitrous oxide, enflurane and analgesic agents, e.g. pethidine, buprenorphine. No pharmacological interactions have been encountered.

Use during Pregnancy and Lactation:
Propofol has not been used in dogs and cats where the pregnancy is to be maintained, but has been used successfully for induction prior to Caesarean section in bitches.
The safety of Propofol in fetuses/neonates and during lactation has not been established.
Use only according to the benefit/risk assessment by the responsible veterinarian.

User Warnings:
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 case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

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

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

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.

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

Any unused veterinary 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

February 2023

15. OTHER INFORMATION

ManA 2000

LEGAL CATEGORY:

PACKAGING QUANTITIES:

Vials of 20 ml and 50 ml.
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. pethidine, buprenorphine. No pharmacological interactions have been encountered. The emulsion should not be mixed with other therapeutic agents or infusion fluids prior to administration.

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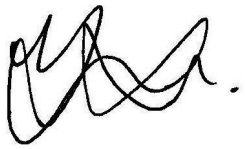
FOR ANIMAL TREATMENT ONLY



Approved: 22 February 2023