PARTICULARS TO APPEAR ON THE OUTER PACKAGE

20ML/50ML CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetofol 1.0% w/v Emulsion for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1.0% w/v propofol

3. PHARMACEUTICAL FORM

A white, aqueous, isotonic emulsion

4. PACKAGE SIZE

Vials of 20 ml and 50 ml

5. TARGET SPECIES

Dogs and Cats

6. INDICATION(S)

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.

Vetofol Injection is particularly suitable for cases where a short recovery period is desired.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The product is indicated for intravenous administration to dogs and cats. Shake the vial gently but thoroughly before opening. Do not use if evidence of phase separation remains after gentle shaking. Vetofol Injection should not be mixed with other products.

For dosage read the package leaflet before use.

8. WITHDRAWAL PERIOD

<Not Applicable>

9. SPECIAL WARNING(S), IF NECESSARY

Contraindications: None

Warnings:

During induction of anaesthesia, mild hypotension and transient apnoea, similar to effects with other intravenous anaesthetic agents may occur. When using Vetofol 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.

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.

If Vetofol Injection is injected very slowly, an inadequate plane of anaesthesia can occur.

Side-Effects:

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.

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.

Overdose:

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.

OPERATOR 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 the event of accidental self- administration, seek urgent medical attention and show the label.

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

10. EXPIRY DATE

DOM:
EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.

Do not freeze.

Avoid introduction of contamination.

Withdrawn product should be used immediately. Product remaining in the container should be discarded.

Keep container in 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

FOR ANIMAL TREATMENT ONLY

Legal Category | POM-V |

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

MANUFACTURED BY:

Norbrook Laboratories Limited
NEWRY
Co. Down
Northern Ireland

DISTRIBUTED BY:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ
Co Down
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4244

17. MANUFACTURER'S BATCH NUMBER

B.N.:

UK AUTHORISED VETERINARY MEDICINAL PRODUCT

FURTHER INFORMATION:

Read the package leaflet before use.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

50ML VIAL LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetofol 1.0% w/v Emulsion for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1.0% w/v propofol

3. PHARMACEUTICAL FORM

Emulsion for Injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Cats and Dogs.

6. INDICATION(S)

Injectable Anaesthetic

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous use only.

Shake the vial gently but thoroughly before opening.

For dosage, read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not Applicable

9. SPECIAL WARNING(S), IF NECESSARY

This is a potent drug: avoid self-administration. Read package leaflet for full user warnings. Keep the container in the outer carton.

Do not use if evidence of phase separation remains after gentle shaking.

10. EXPIRY DATE

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.

Do not freeze.

Withdrawn product should be used immediately. Product remaining in the container should be discarded.

Avoid the introduction of contamination.

Keep container in 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

FOR ANIMAL TREATMENT ONLY

POM-V	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

Manufactured by:

Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

Distributed by:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ
Co Down
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4244

ManA 2000

17. MANUFACTURER'S BATCH NUMBER

BN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

20ML VIAL LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetofol 1.0% w/v Emulsion for Injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1.0% w/v propofol

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

20 ml

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

POM-V

To be supplied only on veterinary prescription

9. SPECIAL WARNINGS

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

10. EXPIRY DATE

Exp.: dd/mm/yy

11. SPECIAL STORAGE CONDITIONS

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

For disposal advice refer to package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

FOR ANIMAL TREATMENT ONLY

POM-V	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

Manufactured by:

Norbrook Laboratories Limited
Newry
Co. Down
Northern Ireland

Distributed by:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ
Co Down
Northern Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4244

ManA 2000

17. MANUFACTURER'S BATCH NUMBER

BN:

PACKAGE LEAFLET FOR: VETOFOL 1.0% W/V EMULSION FOR INJECTION

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

MANUFACTURED BY:

Norbrook Laboratories Limited
NEWRY
Co. Down
Northern Ireland

DISTRIBUTED BY:

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
BT35 6QQ
Co Down
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetofol 1.0% w/v Emulsion for Injection

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

1.0% w/v propofol

4. INDICATION(S)

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.

Vetofol Injection is particularly suitable for cases where a short recovery period is desired.

5. CONTRAINDICATIONS

None

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.

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.

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, ROUTE(S) AND METHOD OF ADMINISTRATION

The product is indicated for intravenous administration to dogs and cats.

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. 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 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.

9. ADVICE ON CORRECT ADMINISTRATION

Shake the vial gently but thoroughly before opening. Do not use if evidence of phase separation remains after gentle shaking. Vetofol Injection should not be mixed with other products.

10. WITHDRAWAL PERIOD(S)

<Not Applicable>

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Protect from light. Do not freeze.

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.

Keep container in outer carton.

12. SPECIAL WARNING(S)

During induction of anaesthesia, mild hypotension and transient apnoea, similar to effects with other intravenous anaesthetic agents may occur. When using Vetofol 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.

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.

If Vetofol Injection is injected very slowly, an inadequate plane of anaesthesia can occur.

Overdose:

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.

OPERATOR 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 the event of accidental self- administration, seek urgent medical attention and show the label.

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

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

October 2022

<15. OTHER 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 incompatibility has been encountered.

Inadvertent perivascular administration rarely causes local tissue reactions.

PACKAGING QUANTITIES:

Vials of 20 ml and 50 ml

Not all package sizes may be presented.

ManA 2000

Marketing Authorisation No.: Vm 02000/4244

Legal Category

POM-V

To be supplied only on veterinary prescription.

For Animal Treatment Only.

Approved 28 October 2022