ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Somulose Solution for injection
Secobarbital sodium, Cinchocaine hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains: Active substances: Secobarbital sodium (Quinalbarbitone) 400 mg, Cinchocaine hydrochloride 25 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

25 ml, 50 ml

5. TARGET SPECIES

Cats, dogs, horses and cattle.

6. INDICATION

For the euthanasia of cats, dogs, horses and cattle.

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.
Recommended dosage: By intravenous administration only. Dogs and cats: 0.25 ml/kg, horses and cattle: 1.0 ml/10 kg
N.B. Speed of injection is very important. Administer the full dose over 10-15 seconds in order to minimise premature cardiac arrest. Additionally, an injection rate that is too slow may induce normal collapse, but prolong the period until death. Use of an intravenous catheter is recommended.

8. WITHDRAWAL PERIOD

Not for use in animals intended for human or animal consumption due to the risk of secondary intoxication. Treated animals may never be slaughtered for human or animal consumption. Horses must have been declared as not intended for human consumption under national horse passport legislation.

9. SPECIAL WARNINGS

Special warnings:
Avoid accidental self-injection. Seek medical attention immediately if accidentally self-injected.
Must not be used for anaesthesia; non-sterile.
Do not use if the solution is not clear or if any sediment is observed.
Directions for use: (25 ml) Read package leaflet before use; (50 ml) See inside of lid.
Following withdrawal of the first dose, use the product within 60 days.
Discard unused material.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 60 days.
Once opened used by…

11. SPECIAL STORAGE CONDITIONS

Keep container in outer carton. **Do not store above 25ºC.**
Do not refrigerate or freeze.
Protect from frost. Protect from light.

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

Any unused veterinary medicinal products or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. It is strongly recommended that carcasses of animals euthanased with Somulose are incinerated.

UK only: Dispose of any unused product in accordance with the Misuse of Drugs Regulations 2001.

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

For animal treatment only.

UK only: To be supplied only on veterinary prescription.

(Sch. 2) CD

UK POM-V

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

Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 10434/4010

17. MANUFACTURER'S BATCH NUMBER

Lot

18. OTHER INFORMATION

Veterinary medicinal product authorised for use in UK.

(For 50 ml pack size only):
Large animal euthanasia kit
This pack contains:
50 ml Somulose Solution for injection
50 ml syringe
14 gauge sterile catheter
Mini-spike dispensing pin

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Somulose Solution for injection
Secobarbital sodium, Cinchocaine hydrochloride

2. QUANTITY OF THE ACTIVE SUBSTANCES

1 ml contains: Active substances: Secobarbital sodium (Quinalbarbitone) 400 mg, Cinchocaine hydrochloride 25 mg

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

25 ml, 50 ml

4. ROUTES OF ADMINISTRATION

Recommended dosage: By intravenous injection only.
Dogs and cats: 0.25 ml/kg; Horses and cattle: 1.0 ml/10 kg.
N.B. Speed of injection is very important. Administer the full dose over 10–15 seconds in order to minimise premature cardiac arrest. Additionally, an injection rate that is too slow may induce normal collapse, but prolong the period until death. Use of an intravenous catheter is recommended.

5. WITHDRAWAL PERIOD

Not for use in animals intended for human or animal consumption due to the risk of secondary intoxication. Treated animals may never be slaughtered for human or animal consumption. Horses must have been declared as not intended for human consumption under national horse passport legislation.

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}
Once opened used by…

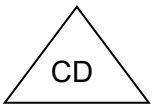
8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

9. OTHER INFORMATION

Vm 10434/4010

For the euthanasia of cats, dogs, horses and cattle.



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UK | POM-V

Keep out of the sight and reach of children.
Contraindications and warnings: Read package leaflet before use.
Special warnings: Avoid accidental self-injection. Seek medical attention immediately if accidentally self-injected.
Must not be used for anaesthesia; non-sterile.
Directions for use: Read package leaflet before use.
Do not use if the solution is not clear or if any sediment is observed. Following withdrawal of the first dose use the product within 60 days. Discard unused material. Keep container in outer carton. **Do not store above 25ºC. Do not refrigerate or freeze. Protect from frost. Protect from light.**
Any unused veterinary medicinal products or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements (UK). It is strongly recommended that carcasses of animals euthanased with Somulose are incinerated.

Discard after:

Dechra Limited

UK only: Dispose of any unused product in accordance with the Misuse of Drugs Regulations 2001.
To be supplied only on veterinary prescription.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Somulose solution for injection

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

Marketing authorisation holder:
Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

Manufacturers responsible for batch release:
Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
Netherlands

Dales Pharmaceuticals
Snaygill Industrial Estate
Keighley Road, Skipton
North Yorkshire
BD23 2RW

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Somulose Solution for injection
Secobarbital sodium, Cinchocaine hydrochloride

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 ml contains: Active substances:
Secobarbital sodium (Quinalbarbitone) 400 mg/ml
Cinchocaine hydrochloride 25 mg/ml
A clear, straw coloured solution for injection.

4. INDICATION

Somulose is indicated for the euthanasia of cats, dogs, horses and cattle.
Secobarbitone is a hypnotic derivative of barbituric acid with a rapid onset of action, which profoundly depresses the central nervous system, including the respiratory centres.
Cinchocaine has marked cardiotoxic effects at high doses.
When given in combination, the barbiturate produces rapid loss of consciousness and cessation of respiration while the cinchocaine depresses the cardiac conduction resulting in early cardiac arrest. Since cardiac arrest is not dependent on

development of profound hypoxia, euthanasia with Somulose is generally not accompanied with the gasping which may occur with other agents.

5. CONTRAINDICATIONS

The combination product must not be used for anaesthesia; it is non-sterile.

6. ADVERSE REACTIONS

The recommended dose may be insufficient to achieve rapid euthanasia in some horses and this has been rarely reported. Excitation, muscle tremor and convulsion after injection has been very rarely observed in horses. Sedation prior to euthanasia is recommended in horses. See 'Advice on correct administration'.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

7. TARGET SPECIES

Cats, dogs, horses and cattle.

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

For intravenous administration only.
Recommended dose: Dogs and cats intravenously: 0.25 ml/kg body weight.
Horses and cattle intravenously: 1.0 ml/10 kg body weight.

9. ADVICE ON CORRECT ADMINISTRATION

N.B. Speed of injection is very important. Administer the full dose over 10–15 seconds, in order to minimise premature cardiac arrest. Additionally, an injection rate that is too slow may induce normal collapse, but prolong the period until death. It is always advisable to have an alternative method of euthanasia available.
As with other methods of euthanasia, care should be taken not to excite the animal during preparation. Many authorities recommend that the procedure should be carried out in familiar surroundings, avoiding harsh lights and sudden noises where possible. During the preparation and administration, it is often helpful to handle the animal carefully, but firmly, comforting it with gentle talk and coaxing as one would for the quiet induction of anaesthesia. This can also serve to calm apprehensive animals.
Once the required dose has been withdrawn from the vial, the mini-spike or needle should be removed from the syringe and discarded into a closed container. A sterile catheter should then be inserted into the injection site, and the syringe connected to it. Perivascular administration of secobarbitone may delay the onset of effect and cause pain and result in excitement. Placement of a venous catheter is therefore

recommended and care should be taken to ensure (by aspiration) that the injection is correctly placed in the vein.
In horses and cattle the use of a pre-placed 14 gauge jugular catheter is strongly recommended. In horses, the administration of detomidine, or suitable alternative, by slow IV injection is recommended to produce profound sedation prior to euthanasia. However, this may produce a slower onset of euthanasia.

10. WITHDRAWAL PERIOD

Not to be used in animals intended for human or animal consumption due to the risk of secondary intoxication. Treated animals may never be slaughtered for human or animal consumption. Horses must have been declared as not intended for human consumption under national horse passport legislation.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25ºC.
Do not refrigerate or freeze.
Protect from frost.
Protect from light.
When the container is broached for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided. Shelf life after first opening the immediate packaging: 60 days. Discard unused material.
Do not use if the solution is not clear or if any sediment is observed.
Keep the container in the outer carton.
Do not use this veterinary medicinal product after expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This is a potent drug which is highly toxic in man. Extreme care should be taken to avoid accidental self-administration. Use an intravenous catheter instead of a needle whenever possible.
Due to rapid onset of secobarbitone effect if accidentally self-administered, this product should only be administered in the presence of an assistant/other individual.
Wear suitable protective gloves when handling the product. Wash off splashes from skin and eyes immediately. Wash hands after use. In the event of accidental self-administration, by injection or skin absorption, seek urgent medical assistance advising medical service of barbiturate and local anaesthetic poisoning and show the label.
ADVICE TO DOCTOR: Do not leave patient unattended. Maintain airways and give symptomatic and supportive treatment.
Cinchocaine can cause hypersensitivity following skin contact. Hypersensitivity to cinchocaine may lead to contact dermatitis, which can become severe.
Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.

Handle this product with great care to avoid exposure, taking all recommended precautions.
If you develop symptoms following exposure, such as skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes, or difficulty breathing may occur, although these have not been reported and are more serious symptoms that require urgent medical attention.

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

Any unused veterinary medicinal products or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements (UK and IE). It is strongly recommended that carcasses of animals euthanased with Somulose are incinerated.

UK: Dispose of any unused product in accordance with the Misuse of Drugs Regulations 2001.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2022

15. OTHER INFORMATION

UK: POM-V Prescription Only Medicine - Veterinarian Vm 10434/4010
To be supplied only on veterinary prescription.

CD (Sch. 2)

Vials containing 25 ml and 50 ml. Not all pack sizes may be marketed.

For animal treatment only.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 14 November 2022