1. NAME OF VETERINARY MEDICINAL PRODUCT

Somulose Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:
Active substances:

Secobarbital Sodium (Quinalbarbitone Sodium)	400 mg
Cinchocaine Hydrochloride	25 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for Injection
Clear, slightly straw coloured viscous solution

4. CLINICAL PARTICULARS

4.1 Target species

Dogs, cats, horses and cattle.

4.2 Indications for use, specifying the target species

For euthanasia in dogs, cats, horses and cattle only.

4.3 Contraindications

The combination product must not be used for anaesthesia, it is non-sterile.
When used in horses or cattle do not use the carcass for animal consumption.

4.4 Special warnings for each target species

Non-vascular administration may delay onset of effect, cause pain and result in excitement. Rarely, horses may show resistance to euthanasia and prior use of sedation should be considered in each case (see also under section 4.9). It is always advisable to have an alternative method of euthanasia available.

4.5 Special precautions for use

(i) Special precautions for use in animals

Care should be taken not to excite the animal. The dose is to be administered intravenously only (see also under section 4.9).
It is strongly recommended that carcasses of animals euthanased with Somulose are incinerated.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

Somulose is a potent drug which is highly toxic to man. Extreme care should be taken to avoid accidental self-injection. Use an intravenous catheter instead of a needle whenever possible.
Wear suitable protective gloves when handling the product. Wash off splashes from skin and eyes immediately. Wash hands after use.
Due to the rapid onset of action of secobarbitone if accidentally self-administered, this product should only be administered in the presence of an assistant/other individual.
Once the required dose has been withdrawn from the vial, the mini-spike, or needle, should be removed from the syringe and discarded into a closed container.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 be inserted into the vein and the syringe connected to it. Particular care should be taken in large and/or fractious animals. Do not approach any animal with an unguarded needle on a full syringe.
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.

4.6 Adverse reactions (frequency and seriousness)

Rarely in horses, the dose may be insufficient to achieve rapid euthanasia. See also under section 4.9 for prior use of sedation.

4.7 Use during pregnancy, lactation or lay

Can be used in pregnancy or lactation for euthanasia.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The product is for intravenous injection only.
Recommended dose:
Dogs and cats intravenously: 0.25 ml/kg body weight.
Horses and cattle intravenously: 1.0 ml/10 kg body weight.

Administration: 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.

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.

N.B. The 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.

Do not use if solution is not clear or if any sediment is observed.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not known.

4.11 Withdrawal period

Not to be used in animals intended for human or animal consumption.
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.

5. PHARMACOLOGICAL PARTICULARS

ATC Vet Code: QN05CB02
Pharmacotherapeutic group**:** Barbiturates in combination with other drugs

5.1 Pharmacodynamic properties

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 cardiac conduction resulting in early cardiac arrest. Since cardiac arrest is not dependent on the development of profound hypoxia, euthanasia with the combination is generally not accompanied with the gasping which may occur with other agents.

5.2 Pharmacokinetic properties

In practice the pharmacokinetics are not relevant, since the death of the animal will have occurred prior to clearance of the drug from the body.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene glycol
Ethanol
Water for injection

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 60 days.

6.4 Special precautions for storage

Do not store above 30ºC.
Do not refrigerate or freeze. Protect from frost. Protect from light.
Following withdrawal of the first dose, use the product within 60 days.
Discard unused material.
Do not use if the solution is not clear or if any sediment is observed.

6.5 Nature and composition of immediate packaging

25 ml and 50 ml in amber type I glass vials, with red chlorobutyl rubber stoppers and aluminium seals in cardboard box cartons.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

Disposal of this product is controlled by the Misuse of Drugs Regulations 2001 (UK only).

7. MARKETING AUTHORISATION HOLDER

Dechra Limited
Dechra House
Jamage Industrial Estate
Talke Pits
Stoke-on-Trent
Staffordshire
ST7 1XW
UK

8. MARKETING AUTHORISATION NUMBERS

UK: Vm 10434/4010
IE: VPA 10799/2/1

9. DATE OF FIRST AUTHORISATION

UK: 08 March 2004
IE: 06 October 2006

10. DATE OF REVISION OF TEXT

May 2014

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Somulose Solution for Injection.

2. STATEMENT OF ACTIVE AND OTHER 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

By intravenous injection only. Read the package leaflet before use.
Recommended dosage: 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.

8. WITHDRAWAL PERIOD

Not for use in animals intended for human or animal consumption. 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

Warnings:
Avoid accidental self-injection.
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}

11. SPECIAL STORAGE CONDITIONS

Do not store above 30ºC.
Do not refrigerate or freeze.
Protect from frost. Protect from light.
Keep container in outer carton.

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

Do not use if the solution is not clear or if any sediment is observed. Dispose of part used product and empty containers in accordance with national 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.

CD (Sch .2)

POM-V UK

VPO IE

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Dechra Limited, Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, United Kingdom.

16. MARKETING AUTHORISATION NUMBERS

UK: Vm 10434/4010
IE: VPA 10799/2/1

17. MANUFACTURER'S BATCH NUMBER

Lot

18. OTHER INFORMATION

Veterinary medicinal product authorised for use in UK and Ireland.
Not all pack sizes may be marketed.

(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.

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. 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

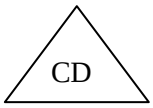
EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

9. OTHER INFORMATION

UK: Vm 10434/4010
IE: VPA 10799/2/1
Somulose is indicated for the euthanasia of cats, dogs, horses and cattle



POM-V UK

VPO IE

Keep out of the sight and reach of children.

Contraindications and warnings: Read package leaflet before use.

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. Dispose of part used product and empty containers in accordance with national requirements. It is strongly recommended that carcasses of animals euthanased with Somulose are incinerated.

Do not store above 30ºC. Protect from frost. Do not refrigerate or freeze. Protect from light.

Following withdrawal of the first dose use the product within 60 days. Discard unused material. Keep container in outer carton.

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.

PACKAGE LEAFLET

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, Dechra House, Jamage Industrial Estate, Talke Pits, Stoke-on-Trent, Staffordshire, ST7 1XW, United Kingdom
Manufacturer for the batch release:
Dales Pharmaceuticals, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Somulose Solution for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 ml contains: Active substance:
Secobarbital Sodium (Quinalbarbitone) 400 mg/ml
Cinchocaine Hydrochloride 25 mg/ml
A clear, straw coloured solution for injection.

4. INDICATION

Indications:
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

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.

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. 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 30ºC.
Do not refrigerate or freeze.
Protect from frost.
Protect from light.
When the container is broached for the first time, the date on which any product remaining in the container should be discarded should be calculated. This discard date should be written in the space provided on the label.
Following withdrawal of the first dose, use the product within 60 days.
Discard unused material.
Do not use if the solution is not clear or if any sediment is observed.
Keep container in outer carton.

12. SPECIAL WARNINGS

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.
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.
Wash hands after use.

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

Disposal: Dispose of part used product and empty containers in accordance with national 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

CD (Sch .2)

POM-V
VPO

UK: Prescription Only Medicine - Veterinarian

IE: Veterinary Practitioner Only

UK only: To be supplied only on veterinary prescription.

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

For animal treatment only.
UK: Vm 10434/4010 IE: VPA 10799/2/1
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder:

Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom