Summary of Product Characteristics

1 NAME OF THE 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

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.

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Once the required dose has been withdrawn from the vial, the mini-spike, or needle, should be removed from the syringe and discarded into a closed container.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 interactions

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 bodyweight
Horses and cattle intravenously: 1.0 ml/10 kg bodyweight
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 preplaced 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 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(s)

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 or IMMUNOLOGICAL PROPERTIES

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 particulars

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 Major 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 30°C.
Do not refrigerate or freeze. Protect from frost. Protect from light.

Following withdrawl 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 products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with national requirements (UK and IE).
Disposal of this product is controlled by the Misuse of Drugs Regulations 2001 (UK only).

7 MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA22622/018/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 October 2006
Date of last renewal: 19 February 2010

10 DATE OF REVISION OF THE TEXT

January 2019