SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Somulose 400 mg/ml + 25 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Secobarbital Sodium	400 mg
Cinchocaine Hydrochloride	25 mg

Excipients:

Qualitative composition of excipients and other constituents
Propylene glycol
Ethanol
Water for injection

Clear, slightly straw coloured viscous solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats, horses and cattle.

3.2 Indications for use for each target species

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

3.3 Contraindications

The combination product must not be used for anaesthesia, it is non-sterile.
Do not use the carcass for animal consumption due to the risk of secondary intoxication.

3.4 Special warnings

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 section 3.9). It is always advisable to have an alternative method of euthanasia available.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Care should be taken not to excite the animal. The dose is to be administered intravenously only (see also section 3.9).

It is strongly recommended that carcasses of animals euthanased with the veterinary medicinal product are incinerated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The veterinary medicinal product 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.

Personal protective equipment consisting of impermeable gloves should be worn when handling the veterinary medicinal 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Once the required dose has been withdrawn from the vial, the mini-spike, or needle, should be removed from the syringe and discarded into a closed container.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 case of accidental self-administration, by injection or skin absorption, seek medical advice immediately advising the medical service of barbiturate and local anaesthetic poisoning and show the package leaflet or the label to the physician.

To the physician: 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, seek medical advice immediately and show the package leaflet or the label to the physician. 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses:

Rare (1 to 10 animals / 10,000 animals treated):	Lack of efficacy[a]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Excitation Muscle tremor, Convulsion

[a] The recommended dose may be insufficient to achieve rapid euthanasia

Sedation prior to euthanasia is recommended in horses (see also section 3.9).

Dogs, cats and cattle:
None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used in pregnancy or lactation for euthanasia.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intravenous use.
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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Not known.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable

3.12 Withdrawal periods

Not authorised 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QN05CB02.

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 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.

5.3 Special precautions for storage

Do not store above 25ºC.
Do not refrigerate or freeze.
Protect from frost.
Protect from light.

5.4 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.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

7. MARKETING AUTHORISATION NUMBERS

Vm 50406/3023

Vm 50406/5028

8. DATE OF FIRST AUTHORISATION

08 March 2004

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

August 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 22 December 2025