1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Menbutil, 100 mg/ml solution for injection for cattle, pigs, horses, sheep and goats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Menbutone 100.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Chlorocresol	2.0 mg
Sodium metabisulphite (E 223)	2.0 mg
Edetic acid (E 385)	
Ethanolamine	
Water for injections	

Clear, slightly yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs, horses, sheep and goats.

3.2 Indications for use for each target species

Stimulation of hepato-digestive activity in case of digestive disorders and hepatic insufficiency.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals with cardiac disease or in the late stages of pregnancy.
Please refer to section 3.7 “Use during pregnancy, lactation or lay”.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Slow intravenous administration is advised (not less than 1 minute) to avoid the side effects described in section 3.6.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not eat, drink or smoke while handling the veterinary medicinal product.
People with known hypersensitivity to menbutone should avoid contact with the veterinary medicinal product.

Accidental self-injection can induce irritation.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle, pigs, horses, sheep and goats:

Rare (1 to 10 animals / 10,000 animals treated):	Recumbency[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reactions[2] Injection site oedema[3,4], injection site haemorrhage[3,4], injection site necrosis[3,4] Lacrimation[4,6] Tremor[5,6]
Undetermined frequency (cannot be estimated from the available data):	Ptyalism[6], involuntary defecation[6] Involuntary urination[6] Restlessness Tachypnoea

[1] transient, especially in cattle and following rapid intravenous injection
[2] should be treated symptomatically
[3] after intramuscular administration
[4] frequency only determined for cattle
[5] frequency only determined for cattle and horses
[6] after intravenous administration

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 also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not use during the last third of pregnancy.

Lactation:
Can be used during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration route and dosage

Intramuscular use, intravenous use.

Calves (up to 6 months), sheep, goats and pigs: deep intramuscular or slow intravenous administration
Cattle, horses: slow intravenous administration

Calves (up to 6 months), sheep, goats and pigs:

10 mg menbutone per kg body weight, equivalent to 1 ml of solution for injection per 10 kg body weight.

Cattle:
5 - 7.5 mg menbutone per kg body weight, equivalent to 1 ml of solution for injection per 15 - 20 kg body weight.

Horses:
2.5 - 5 mg menbutone per kg body weight, equivalent to 1 ml of solution for injection per 20 - 40 kg body weight.

It is recommended not to inject intramuscularly more than 20 ml on one application site.

The veterinary medicinal product administration may be repeated once if necessary after 24 hours.

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

The recommended dosages have to be strictly considered, since the safety factors of menbutone are not known. Cardiovascular drugs should be used in case of a heart block.

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

Meat and offal: Zero days
Milk: Zero days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:
QA05AX90

4.2 Pharmacodynamics
Menbutone, or genabilic acid, is a derivative of oxybutyric acid which acts as a choleretic. After injection into the body, it increases the secretion of the bile, the gastric juice, and the pancreatic juice to 2 to 5 times compared to the normal levels of secretion. Thus, it promotes transit and assimilation of food, and acts as a hepatic detoxifying agent.

4.3 Pharmacokinetics
In cows one hour after intravenous injection, 20 mg/L of menbutone were measured in plasma. After 8 hours, the plasma concentrations were lower than 1 mg/L. 40.4% of the oral dose and 12% of the intravenous dose were excreted in the urine within 24 hours. In milk, a maximum concentration of 0.7 to 0.8 mg/L was reported at about five hours after injection. At or before 14 hours, menbutone concentrations had fallen to 0.1 mg/L or less.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with solutions which contain:
- Calcium
- Procain Penicillin

- Vitamin B complex

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: 28 days.

5.3 Special precautions for storage

Do not store above 25°C.

5.4 Nature and composition of immediate packaging

Multidose clear type I glass vial of 100 ml with bromobutyl rubber stopper and aluminium crimp caps in a cardboard box.

Pack sizes:
Cardboard box with 1 x 100 ml or 12 x 100 ml.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

aniMedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10826/023/001

8. DATE OF FIRST AUTHORISATION

14/12/2018

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

08/11/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).