Summary of Product Characteristics

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:		
Chlorocresol	2.0	mg
Sodium metabisulphite (E 223)	2.0	mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
Clear, slightly yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, pigs, horses, sheep and goats.

4.2 Indications for use, specifying the target species

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

4.3 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 4.7 Use during pregnancy, lactation or lay.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Slow intravenous administration is advised (not less than 1 minute) to avoid the side effects described in section 4.6.

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

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

Do not eat, drink or smoke while handling the 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.

4.6 Adverse reactions (frequency and seriousness)

After intravenous administration, salivation, lacrimation, tremors, spontaneous urination and defecation may occur.
After intramuscular administration, reaction at the injection site (oedema, haemorrhage, necrosis) may occur.
Restlessness and increased respiratory frequency is occasionally observed.
In rare cases transient recumbency may occur, especially in cattle and following rapid intravenous injection.
In very rare cases anaphylactic-type reactions may occur and should be treated symptomatically.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals 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).

4.7 Use during pregnancy, lactation or lay

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

Lactation:
This product may be given to lactating animals.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Calves (up to 6 months), sheep, goats and pigs:
10 mg menbutone per kg body weight either via deep intramuscular or slow intravenous administration, equivalent to 1 ml of solution for injection per 10 kg body weight.

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

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

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

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

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.

4.11 Withdrawal period(s)

Meat and offal: Zero days
Milk: Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Alimentary tract and metabolism, other drugs for bile therapy.

ATCvet code: QA05AX90

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Edetic acid (E385)
Sodium metabisufit (E233)
Chlorocresol
Ethanolamine
Water for injections

6.2 Major incompatibilities

Not to administer together with solutions which contain:

- Calcium
- Procain Penicillin
- Vitamin B complex

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: 28 days

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Multidose clear type I glass vial of 100 ml with bromobutyl rubber stopper and aluminium crimp caps. Box with 1 x 100 ml or 12 x 100 ml.

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 product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10826/023/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14th December 2018

10 DATE OF REVISION OF THE TEXT

March 2020