

ANNEX I
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
[AT, BE, BG, CY, CZ, DE, EE, EL, ES, FR, HU, IE, IS, IT, LT, LV, NL, PL, PT, RO, SI, SK]

Ganutil, 100 mg/ml solution for injection for cattle, pigs, horses, sheep and goats [DK, SE, NO]

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 choleric. 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)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

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

{MM/YYYY}

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Menbutil, 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml solution contains:

Active substance:

Menbutone 100.0 mg

3. PACKAGE SIZE

100 ml

12 x 100 ml

4. TARGET SPECIES

Cattle, pigs, horses, sheep and goats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular: Calves, pigs, sheep and goats

Intravenous: Cattle, calves, pigs, horses, sheep and goats

Slow intravenous administration is advised.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: Zero days

Milk: Zero days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Menbutil, 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Menbutone 100.0 mg

3. TARGET SPECIES

Cattle, pigs, horses, sheep and goats.

4. ROUTES OF ADMINISTRATION

Intravenous and intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: Zero days
Milk: Zero days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.

Once opened, use by:

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:

Menbutone 100.0 mg

Excipients:

Chlorocresol 2.0 mg

Sodium metabisulphite (E 223) 2.0 mg

Clear, slightly yellow solution.

3. Target species

Cattle, pigs, horses, sheep and goats.

4. Indications for use

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

5. 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 also to section "Special warnings - Pregnancy".

6. Special warnings

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 "Adverse events".

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.

Pregnancy:

Do not use during the last third of pregnancy.

Lactation:

Can be used during lactation.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

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.

Major incompatibilities:

Do not mix with solutions which contain:

- Calcium
- Procain Penicillin
- Vitamin B complex

7. 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 (injection site swelling) ^{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 (hypersalivation) ⁶ , involuntary defecation ⁶ Involuntary urination ⁶ Restlessness Tachypnoea (rapid breathing)

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. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

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.

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

9. Advice on correct administration

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

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

10. Withdrawal periods

Meat and offal: Zero days

Milk: Zero days

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

XXXXXXXXXXXX

Pack sizes:

Cardboard box with 1 x 100 ml or 12 x 100 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany
Tel: +49-2536-3302-0

Manufacturer responsible for batch release:

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Industrial Veterinaria, S.A.
Esmeralda 19
08950 Esplugues de Llobregat (Barcelona)
Spain

Local representatives and contact details to report suspected adverse reactions: