1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alvebuton 100 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Menbutone 100.00 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	2.00 mg
Sodium metabisulfite (E223)	2.00 mg
Edetic acid	
Ethanolamine	
Water for injections	

Clear, pale yellow to yellow solution

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs, horses, sheep, 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:

For horses only slow intravenous administration.

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

Accidental self-injection can induce irritation.
People with known hypersensitivity to menbutone should avoid contact with the veterinary medicinal product. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not eat, drink or smoke while handling this veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, pigs, horses, sheep, goats:

Rare (1 to 10 animals / 10,000 animals treated):	Recumbency[1]
Undetermined frequency (cannot be estimated from available data):	Injection site oedema[2], Injection site haemorrhage[2], Injection site necrosis[2] Restlessness Increased salivation[3], Involuntary defecation[3] Lacrimation[3] Muscle tremor[3] Involuntary urination[3] Increased respiratory rate

[1] especially in cattle and following rapid intravenous injection
[2] after intramuscular administration
[3] 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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Do not use during the last third of pregnancy. The veterinary medicinal product may be used during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Calves, sheep, goats and pigs: Intramuscular (i.m.) or intravenous (i.v.) injection.
Cattle: intravenous injection.
Horses: slow intravenous use.

Calves (up to 6 months), sheep, goats and pigs:
10 mg menbutone per kg body weight i.m. or i.v., equivalent to 1 ml of solution for injection per 10 kg body weight.

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

Horses:
2.5 - 5 mg menbutone per kg body weight i.v., equivalent to 1 ml of solution for injection per 20 - 40 kg body weight.
Administration may be repeated once if necessary after 24 hours.
The intravenous administration should be done slowly (not less than 1 minute) to avoid the side effects described in section 3.6

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

None 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

Cattle, pigs, horses, sheep, goats: Meat and offal: zero days
Cattle, horses, sheep, goats: 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 stimulating secretion, a trypsinogen and a pepsinogen. After injection into the body, it increases biliary, pancreatic and peptic secretion by 2 to 5 times compared with the normal levels.
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 was measured in plasma. After 8 hours, the plasma concentrations were lower than 1 mg/L.
The half-life of elimination is estimated at 8 hours for the different species.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with products containing calcium salts, procaine penicillin or B vitamins.

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

Keep the bottle in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Multidose clear type I vial of 100 ml, closed with brombutyl rubber stoppers and aluminium flip caps.
Pack sizes:
Pack of 1 vial of 100 ml solution for injection.
Pack of 10 vials of 100 ml solution for injection.
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

V.M.D. n.v.

7. MARKETING AUTHORISATION NUMBER(S)

VPA16142/003/001

8. DATE OF FIRST AUTHORISATION

24/03/2017

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

27/06/2025

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).