# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Alvebuton 100 mg/ml Solution for injection for cattle, pigs, horses, sheep, goats

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

| | |
|---|---|
| **Active substance:** | |
| Menbutone | 100.00 mg |
| **Excipients:** | |
| Chlorocresol | 2.00 mg |
| Sodium metabisulfite (E 223) | 2.00 mg |

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Solution for injection
Clear, pale yellow to yellow solution

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Cattle, pigs, horses, sheep, goats.

### 4.2 Indications for use, specifying the target species

Cattle, pigs, horses, sheep, goats:
Stimulation of hepato-digestive activity in case of digestive disorders and hepatic insufficiency.

### 4.3 Contraindications

Do not use in known 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
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 product.

**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.

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

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

**4.8 Interaction with other medicinal products and other forms of interactions**

None known.

**4.9 Amounts to be administered and administration route**

Calves, sheep, goats and pigs: Intramuscular or intravenous injection.
Cattle, horses: intravenous injection.

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.

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

None known.

**4.11 Withdrawal period(s)**

| | | |
|---|---|---|
| Cattle, pigs, horses, sheep, goats: | Meat and offal: | zero days |
| Cattle, horses, sheep, goats: | Milk: | zero days |

**5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Alimentary Tract and Metabolism, other drugs for bile therapy, menbutone, ATCvet code: QA05AX90

**5.1 Pharmacodynamic properties**

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 of these.
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.
The half-life of elimination is estimated at 8 am for the different species.

**6 PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Chlorocresol
Sodium metabisufite (E223)
Edetic acid
Ethanolamine
Water for injections

**6.2 Major incompatibilities**

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

**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**

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

**6.5 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 injection solution.
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

V.M.D. n.v.
Hoge Mauw 900
Arendonk
2370
Belgium

## 8 MARKETING AUTHORISATION NUMBER(S)

VPA16142/003/001

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24 March 2017
Date of last renewal: 27 November 2020

## 10 DATE OF REVISION OF THE TEXT

November 2020