

[Version 9.1,11/2024]

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

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 choleric 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)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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**Carton****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Alvebuton 100 mg/ml Solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Menbutone 100.00 mg

3. PACKAGE SIZE

100 ml, 10 x 100 ml

4. TARGET SPECIES**5. INDICATIONS****6. ROUTES OF ADMINISTRATION**

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

Cattle: intravenous injection.

Horses: slow intravenous use.

7. WITHDRAWAL PERIODS

Withdrawal period:

Meat and offal: zero days

Milk: zero days

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days

9. SPECIAL STORAGE PRECAUTIONS

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

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

V.M.D. n.v.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml clear glass vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alvebuton 100 mg/ml Solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Menbutone 100.00 mg

3. TARGET SPECIES



4. ROUTES OF ADMINISTRATION

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

Cattle: intravenous injection.

Horses: slow intravenous use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

Meat and offal: zero days

Milk: zero days

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

Use by...

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

V.M.D. n.v.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Alvebuton 100 mg/ml Solution for injection

2. Composition

Each ml contains:

Active substance:

Menbutone 100.00 mg

Excipients:

Chlorocresol 2.00 mg

Sodium metabisulfite (E223)..... 2.00 mg

Clear, pale yellow to yellow solution.

3. Target species



Cattle, pigs, horses, sheep, 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 to section “Pregnancy and lactation”.

6. Special warnings

Special precautions for safe use in the target species:

For horses only slow intravenous administration.

The intravenous administration should be done slowly (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:

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

People with known hypersensitivity to menbutone should avoid contact with the veterinary medicinal product

Do not eat, drink or smoke while handling this veterinary medicinal product.

Pregnancy and lactation:

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

Interaction with other medicinal products and other forms of interaction:

None known.

Major incompatibilities:

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

7. Adverse events

Cattle, pigs, horses, sheep, goats:

| | |
|--|--|
| Rare (1 to 10 animals / 10,000 animals treated): | Recumbency ^A |
| 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 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:

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

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 .

9. Advice on correct administration

None.

10. Withdrawal periods

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

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the bottle in the outer carton in order to protect from light. Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. 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

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.

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:

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

Manufacturer responsible for batch release:

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

or

Laboratoires BIOVE, 3 Rue de Lorraine, 62510 Arques, France

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien

V.M.D. n.v.

Hoge Mauw 900

BE-2370 Arendonk

Tél/Tel: +32 (0) 14 67 20 51

Deutschland

V.M.D. n.v.

Hoge Mauw 900

BE-2370 Arendonk

Belgien

Tel: +32 (0) 14 67 20 51

España

V.M.D. n.v.

Hoge Mauw 900

BE-2370 Arendonk

Bélgica

Tel: +32 (0) 14 67 20 51

France

Laboratoires Biové

Rue de Lorraine 3

FR-62510 Arques

Tél: +33 32 1982121

Hrvatska

IRIS FARMACIJA d.o.o.

Bednjanska 12,

10000 Zagreb

Tel: +385 (0)91 2575 785

Ireland

V.M.D. n.v.

Hoge Mauw 900

BE-2370 Arendonk

Belgium

Tel: +32 (0) 14 67 20 51

Italia

V.M.D. n.v.

Hoge Mauw 900

BE-2370 Arendonk

Belgio

Tel: +32 (0) 14 67 20 51

Luxembourg/Luxemburg

V.M.D. n.v.

Hoge Mauw 900

BE-2370 Arendonk

Belgique

Tél/Tel: +32 (0) 14 67 20 51

Nederland

V.M.D. n.v.

Hoge Mauw 900

BE-2370 Arendonk

België

Tel: +32 (0) 14 67 20 51

Österreich

V.M.D. n.v.

Hoge Mauw 900

BE-2370 Arendonk

Belgien

Tel: +32 (0) 14 67 20 51

România

Orion Pharma România srl

B-dul T. Vladimirescu nr 22,

București, 050883-RO

Tel: +40 31845 1646

17. Other information