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ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
Menbutone 100.00 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 metabisufite (E223)	2.00 mg
Edetic acid (as disodium edetate)	
Ethanolamine	
Water for injections	

Clear, greenish-yellow solution for injection.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, sheep, goats, horses and pigs.

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 known.

3.5 Special precautions for use

Special precautions for safe use in the target species:

For horses only slow intravenous administration is advised.

The intravenous administration should be done slowly (not less than 1 minute) to avoid the side effects described in section 3.6.
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:

Accidental self-injection can induce local reactions.
People with known hypersensitivity to menbutone should avoid contact with the veterinary medicinal product.
Use a guarded needle until ready for use.
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, sheep, goats, horses, pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Recumbency[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Restlessness Increased respiratory rate
Undetermined frequency (cannot be estimated from the available data)	Tremor[2] Involuntary urination[2] Hypersalivation[2], Involuntary defecation[2] Lacrimation[2] Injection site necrosis[3], Injection site oedema[3], Injection site haemorrhage[3]

[1]It is transient and may occur especially in cattle after rapid intravenous injection.
[2] After intravenous administration.
[3] After intramuscular 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 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 or intravenous use.
Cattle: intravenous use.
Horses: slow intravenous use.

Calves (up to 6 months), sheep, goats and pigs:
10 mg menbutone per kg body weight applied either deeply intramuscular or slowly 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 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.

Administration may be repeated once if necessary after 24 hours.
Do not broach the vial more than 125 times.

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

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 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.

4.3 Pharmacokinetics

In cattle 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 as 8 hours for the different species.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product especially calcium salts, procaine penicillin or B vitamins.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Keep the vial in the outer carton in order to protect from light. This veterinary medicinal product does not require any special temperature storage conditions.

5.4 Nature and composition of immediate packaging

100 ml natural multi-layer (COEX) PP/EVOH/PP vials closed with bromobutyl rubber stopper and aluminium and plastic flip capsule.
Pack size:
Cardboard box with 1 vial of 100 ml.

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

Vet-Agro Multi-Trade Company Sp. z o.o.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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

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)

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetbuton 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
Menbutone 100.00 mg

3. PACKAGE SIZE

1x100 ml

4. TARGET SPECIES

Cattle, sheep, goats, horses and pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Calves, sheep, goats and pigs: intramuscular or intravenous use.
Cattle: intravenous use.
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 by 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial 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

Vet-Agro (logo name of the marketing authorisation holder)

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetbuton 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance:
Menbutone 100.00 mg

3. TARGET SPECIES

Cattle, sheep, goats, horses and pigs

4. ROUTES OF ADMINISTRATION

Calves, sheep, goats and pigs: intramuscular or intravenous use.
Cattle: intravenous use.
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 by 28 days.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Vet-Agro (logo name of the marketing authorisation holder)

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. 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 metabisufite (E223)	2.00 mg

Clear, greenish-yellow solution for injection.

3. Target species

Cattle, sheep, goats, horses and pigs.

4. Indications for use

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

5. Contraindications

Do not use in case 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 “Special warnings”.

6. Special warnings

Special warnings:

None known.

Special precautions for safe use in the target species:

For horses only slow intravenous administration is advised.
The intravenous administration should be done slowly (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.

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

Accidental self-injection can induce local reactions.
People with known hypersensitivity to menbutone should avoid contact with the veterinary medicinal product.
Use a guarded needle until ready for use.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:

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

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

None known.

Major incompatibilities:

Do not mix with any other veterinary medicinal product especially calcium salts, procaine penicillin or B vitamins.

7. Adverse events

Cattle, sheep, goats, horses, pigs:

Rare (1 to 10 animals / 10,000 animals treated):	Recumbency[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Restlessness Increased respiratory rate
Undetermined frequency (cannot be estimated from the available data)	Tremor[2] Involuntary urination[2] Hypersalivation[2], Involuntary defecation[2] Lacrimation[2] Injection site necrosis[3], Injection site oedema[3], Injection site haemorrhage[3]

[1]It is transient and may occur especially in cattle after rapid intravenous injection.
[2] After intravenous administration.
[3] After intramuscular 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: {national system details}

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

Calves, sheep, goats and pigs: intramuscular or intravenous use.
Cattle: intravenous use.
Horses: slow intravenous use.

Calves (up to 6 months), sheep, goats and pigs:
10 mg menbutone per kg body weight applied either deeply intramuscular or slowly 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 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.

Administration may be repeated once if necessary after 24 hours.

9. Advice on correct administration

Do not broach the vial more than 125 times.

10. Withdrawal periods

Meat and offal: zero days
Milk: zero days

11. Special storage precautions

Keep out of the sight and reach of children.
Keep the vial in the outer carton in order to protect from light. This veterinary medicinal product does not require any special temperature storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label 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 size:
Cardboard box with 1 vial of 100 ml.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Vet-Agro Multi-Trade Company Sp. z o.o.
Gliniana 32, 20-616 Lublin, Poland

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information