[Version 8.2, 01/2021]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DIGESTOSYVA 100 mg/ml solution for injection for cattle, sheep, goats, pigs, horses and dogs.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Menbutone	100.0 mg

Excipients:

Chlorocresol	2.0 mg
Sodium metabisulfite (E 223)	2.0 mg
Edetic acid	2.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, slightly yellow solution, free from visible particles.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, sheep, goats, pigs, horses and dogs

4.2 Indications for use, specifying the target species

Indicated, in the following species, for restoration of normal gastrointestinal function in situations where a stimulation of digestive secretions is required, such as:
Cattle: indigestion, food poisoning, ketosis, anorexia.
Sheep and goats: indigestion, toxaemia of pregnancy.
Pigs: indigestion, anorexia, constipation.
Horses: digestive disorders, colic.
Dogs: indigestion, anorexia, constipation.

4.3 Contraindications

Do not use in animals with cardiac disease, hyperthermia or blockage in the bile ducts.
Do not use in cases of hypersensitivity to the active substance or any of the excipients.
Do not use in cats in any case.
Please see section 4.7 Use during pregnancy, lactation or lay.

4.4 Special warnings for each target species

When dealing with an alteration of the digestive system, it is necessary to identify and to treat properly the underlying cause, because, otherwise, treatment with the veterinary medicinal product might not be effective.

4.5 Special precautions for use

Special precautions for use in animals
It is recommended not to inject intramuscularly more than 20 ml on one application site.
In horses only slow intravenous administration is advised.
The intravenous administration of the veterinary medicinal product should be done slowly (not less than 1 minute) to avoid the occurrence of adverse reactions described in paragraph 4.6.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This product is irritating after injection and can cause pain and swelling.
Care should be taken to avoid accidental self-injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
This product can cause eye irritation.
Avoid contact with eyes and wash hands after use.
When the product comes into contact with the eyes, rinse immediately with plenty of water.
Persons with known hypersensitivity to any of the components of the product should avoid contact with the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

Intramuscular administration may cause reaction at the injection site, consisting of necrosis of muscle tissue, oedema and bleeding, sometimes accompanied with pain in very rare occasions. These lesions were microscopically detectable 28 days after administration.
After excessively rapid intravenous administration, tremors, rapid breathing, spontaneous defecation, cough, watery eyes, sneezing and fall of the animal may occur in very rare occasions.

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

Pregnancy:
Do not use during the last third of pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer together with solutions containing calcium salts, procaine penicillin or vitamin B complex.

4.9 Amounts to be administered and administration route

Deep intramuscular or slow intravenous administration. In horses, only slow intravenous administration is recommended.
Dose: 10 mg of menbutone / kg body weight (equivalent to 1 ml of the veterinary medicinal product / 10 kg body weight).
If necessary, a second dose of the product may be administered after 24 hours.

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

The recommended dose should be strictly considered, since the safety margin of menbutone is unknown. Cardiotonic drugs should be used in case of a heart block.

4.11 Withdrawal period(s)

Cattle:
Intramuscular use:
Meat and offal: 2 days
Milk: 2 days
Intravenous use:
Meat and offal: 2 days
Milk: 2 days

Sheep and goats:
Intramuscular and intravenous use:
Meat and offal: 2 days.
Milk: 2 days.

Pigs:
Intramuscular and intravenous use:
Meat and offal: 2 days.

Horses:
Intravenous use:
Meat and offal: 2 days.
Milk: 2 days

5. PHARMACOLOGICAL PROPERTIES

Phamacotherapeutic group: Alimentary tract and metabolism, other drugs for bile therapy.
ATCvet code: QA05AX90

5.1 Pharmacodynamic properties

Menbutone increases from twice to fivefold the secretion of bile, gastric and pancreatic juices into the intestine and stimulates gastrointestinal tract function. The effect is observed within a few minutes of administration and lasts for 2-3 hours.
These actions cause food to be properly digested and absorbed in the intestine in those situations where the secretory function of the digestive system is compromised.

5.2 Pharmacokinetic particulars

In calves, after a single intramuscular dose of 10 mg/ kg of menbutone, a Cmax of 18 µg / ml was reached in 2-4 hours. After 8 hours from the administration, plasma concentrations were below 6 µg / ml. A half-life of 7-8 hours was obtained.
In cows, one hour after administration of 10 mg/ kg of menbutone intravenously, plasma concentration was about 20 µg / ml. These levels decreased to values below 1 µg / ml after 8 hours.
Excretion is largely through urine (up to 40-45% of the administered dose in 48 hours). A small amount is excreted with faeces or milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol.
Sodium metabisulfite E-223.
Ethanolamine.
Edetic acid.
Water for injections

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products .

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

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

6.5 Nature and composition of immediate packaging

Cardboard box with 1 colourless, type I glass vial with a type I bromobutyl rubber stopper and sealed with an aluminium cap.

Package sizes:

Box with 1 vial of 100 ml
Box with 1 vial of 250 ml

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Laboratorios SYVA S.A.U.
Avda. Párroco Pablo Díez,
49-57 (24010) León
Spain

Tel: 0034 987800800
Fax: 0034 987805852
Email: mail@syva.es

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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

10 DATE OF REVISION OF THE TEXT

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be supplied only on veterinary prescription
To be administered by the veterinarian or under veterinarian supervision