

**B. PACKAGE LEAFLET**

## PACKAGE LEAFLET FOR:

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

### 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

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

### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

### 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Each ml contains:

#### Active substance:

Menbutone	100.0 mg
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#### Excipients:

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

*Clear, slightly yellow solution, free from visible particles.*

### 4. INDICATION(S)

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, toxæmia of pregnancy.

**Pigs:** indigestion, anorexia, constipation.

**Horses:** digestive disorders, colic.

**Dogs:** indigestion, anorexia, constipation.

### 5. 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 to any of the excipients.

Do not use in cats in any case.

*Please see section 12: Use during pregnancy, lactation or lay.*

## 6. ADVERSE REACTIONS

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)>

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 inform your veterinary surgeon.

## 7. TARGET SPECIES

Cattle, sheep, goats, pigs, horses and dogs

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

## 9. ADVICE ON CORRECT ADMINISTRATION

It is recommended not to inject intramuscularly more than 20 ml on one application site.

The intravenous administration of the veterinary medicinal product should be done slowly (not less than 1 minute) to avoid the occurrence of adverse reactions.

## 10. 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.

## **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 carton and vial after "EXP". The expiry date refers to the last day of the month.

Shelf-life after first opening the container: 28 days.

## **12. SPECIAL WARNING(S)**

### 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.

### Special precautions for use in animals:

In horses only slow intravenous administration is advised.

### 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.

### Pregnancy:

Do not use during the last third of pregnancy.

### 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.

### Overdose (symptoms, emergency procedures, antidotes):

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.

### Incompatibilities:

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

## **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

**14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

**15. OTHER INFORMATION**

Package sizes:     Box with 1 vial of 100 ml  
                          Box with 1 vial of 250 ml

To be supplied only on veterinary prescription.

To be administered by the veterinarian or under veterinarian supervision.

Not all pack sizes may be marketed.