A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Menbutone 100.0 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml 250 ml

5. TARGET SPECIES

Cattle, sheeps, goats, pigs, horses and dogs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Deep intramuscular or slow intravenous administration. In horses, only slow intravenous administration is recommended.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD (S)

Cattle:

<u>Intramuscular use:</u> Meat and offal: 2 days

Milk: 2 days

<u>Intravenous use:</u>

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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once opened, use by:

Shelf life after first opening the immediate packaging: 28 days.

11. SPECIAL STORAGE CONDITIONS

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.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

Administration by a veterinary surgeon or under their direct responsibility. In case of the intravenous route administration only by veterinary surgeon.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE 1 vial of 100 ml 1 vial of 250 ml 1. NAME OF THE VETERINARY MEDICINAL PRODUCT DIGESTOSYVA 100 mg/ml solution for injection for cattle, sheep, goats, pigs, horses and dogs Menbutone 2. STATEMENT OF ACTIVE SUBSTANCES Each ml contains: **Active substance:** Menbutone 100.0 mg **3.** PHARMACEUTICAL FORM Solution for injection. 4. **PACKAGE SIZE** 100 ml 250 ml 5. **TARGET SPECIES** Cattle, sheep, goats, pigs, horses and dogs

6. INDICATION(S)

Read the package leaflet before use

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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Read the package leaflet before use.

8. WITHDRAWAL PERIOD (S)

Cattle:

<u>Intramuscular use:</u> Meat and offal: 2 days

Milk: 2 days
<u>Intravenous use:</u>
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:

<u>Intravenous use:</u> Meat and offal: 2 days.

Milk: 2 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once opened, use by:

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11. SPECIAL STORAGE CONDITIONS

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16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Batch {number}