ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Cardboard box with vials of 5, 25, 50 or 125 doses.
Vial of 50 or 125 doses.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Inmeva, Suspension for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (2 ml) contains:

Inactivated *Chlamydia abortus* strain A22……RP ≥ 1
Inactivated *Salmonella* Abortusovis strain Sao……..……RP ≥ 1

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

5 doses (10 ml)
25 doses (50 ml)
50 doses (100 ml)
125 doses (250 ml)

5. TARGET SPECIES

Sheep (ewe)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once broached use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

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

Disposal: read package leaflet.

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.

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 Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 17533/4019

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 5 or 25 doses.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

INMEVA, suspension for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose (2 ml) contains:

Inactivated *Chlamydia abortus* strain A22..…….. RP ≥ 1
Inactivated *Salmonella* Abortusovis strain Sao……..……..….. RP ≥ 1

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 doses (10 ml)
25 doses (50 ml)

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
INMEVA, suspension for injection

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 Hipra, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

INMEVA, suspension for injection

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

Each 2 ml dose contains:

Active substances:
Inactivated *Chlamydia abortus* strain A22..…….. RP* ≥ 1
Inactivated *Salmonella enterica* subsp. *enterica* serovar Abortusovis strain Sao……. RP* ≥ 1
*Relative Potency determined by ELISA, using a reference vaccine demonstrated to be efficacious.

Adjuvants:
Aluminium hydroxide (Aluminium)……..... 5.29 mg
DEAE Dextran……..……... 20 mg

Ivory-coloured suspension

4. INDICATION(S)

For active immunization of animals to reduce clinical signs (abortion, stillbirth, early mortality and hyperthermia) caused by *Chlamydia abortus,* abortions caused by *Salmonella* Abortusovis and to reduce shedding of both pathogens from infected animals.

Vaccination covers the whole gestation period, when administered according to the recommended vaccination schedules.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substances, to the adjuvants or to any of the excipients.

6. ADVERSE REACTIONS

A palpable local reaction at the injection site, which may appear approximately 1 week post-vaccination, occurred very commonly in studies. In most cases, the reaction is slight or moderate and subsides within 2 weeks without treatment. In

some isolated cases, these reactions can reach up to 6 cm but rapidly decrease in diameter within 2 days without need for treatment.

An increase in body temperature up to 1.0 ºC occurred very commonly 1 day after vaccination in studies. This slight increase subsided spontaneously within 24 hours.

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

Sheep (ewe)

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

For use in ewes from 5 months of age onwards.
Dose: 2 ml by subcutaneous injection, behind the shoulder in the rib area (lateral thoracic region).

Basic vaccination:
Animals should receive 2 vaccine doses with an interval of 3 weeks. The first dose should be administered at least 5 weeks before artificial insemination or mating; administer the second dose 3 weeks after the first dose.

Revaccination: a single booster dose (2 ml) should be administered 2 weeks before each artificial insemination or mating, but not later than 1 year after initial basic vaccination.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use and occasionally during administration.
Allow the vaccine to reach room temperature (15 - 25 ºC) before administration.
Administer under aseptic conditions. Only sterile syringes and needles should be used.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C - 8 °C).
Do not freeze.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.
Shelf life after first opening the container: 10 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

In farms with recurring reproductive disorders caused by *Chlamydia abortus* and/or *Salmonella* Abortusovis, it would be advisable to maintain a high level of immunity within the flock.

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.

Pregnancy and lactation:
Safety of the vaccination during pregnancy and lactation has been established, as well as efficacy during the second third of gestation. The use is not recommended during the last month of gestation.

Interaction with other medicinal products and other forms of interaction:
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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 surgeon 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

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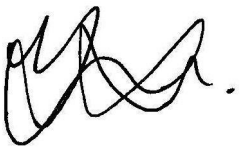
15. OTHER INFORMATION

Cardboard box with 1 PET vial of 5 doses (10 ml).
Cardboard box with 1 PET vial of 25 doses (50 ml).
Cardboard box with 1 PET vial of 50 doses (100 ml).
Cardboard box with 1 PET vial of 125 doses (250 ml).

Not all pack sizes may be marketed.

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



Approved: 31 July 2023