SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

INMEVA, suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection
Ivory-coloured suspension

4. CLINICAL PARTICULARS

4.1 Target species

Sheep (ewe)

4.2 Indications for use, specifying the target species

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 section 4.9.

4.3 Contraindications

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

4.4 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.

4.5 Special precautions for use

Special precautions for use in animals
Not applicable.

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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

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.

4.8 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.

4.9 Amounts to be administered and administration route

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.

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.

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

No information is available.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia).
ATC vet code: QI04AB.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
DEAE Dextran
Simethicone emulsion
Disodium phosphate dodecahydrate
Potassium chloride
Potassium dihydrogen phosphate
Sodium chloride
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 10 hours.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C - 8 °C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Polyethylene (PET) vials of 10, 50, 100 and 250 ml, closed with rubber stopper and aluminium cap.

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.

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

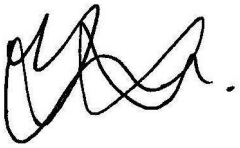
Vm 17533/4019

9. DATE OF FIRST AUTHORISATION

10 June 2019

10. DATE OF REVISION OF THE TEXT

July 2023



Approved: 31 July 2023