1. NAME OF THE VETERINARY MEDICINAL PRODUCT

INMEVA, suspension for injection for sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (2 ml) contains:

Active substances:

Chlamydia abortus strain A22, inactivated	RP* ≥ 1
Salmonella enterica, subsp. *enterica* serovar Abortusovis strain Sao, inactivated	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

Excipients:

Qualitative composition of excipients and other constituents
Simethicone emulsion
Disodium phosphate dodecahydrate
Potassium chloride
Potassium dihydrogen phosphate
Sodium chloride
Water for injections

Ivory-coloured suspension

3. CLINICAL INFORMATION

3.1 Target species

Sheep (ewe)

3.2 Indications for use for each target species

For active immunisation of ewes 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 ewes.

Vaccination covers the whole gestation period, when administered according to section 3.9.

3.3 Contraindications

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

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Sheep (ewe):

Very common (>1 animal / 10 animals treated):	Injection site reaction[1] Elevated temperature[2]

[1]Palpable, approximately one-week post-vaccination, resolution without treatment. In most cases of slight to moderate intensity and abatement within two weeks. In some isolated cases diameter > 6 cm, which decreases within two days without treatment.
[2] Up to 1.0°C one day after vaccination fading spontaneously within 24 hours.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 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.

3.8 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 immunological veterinary medicinal product. A decision to use this vaccine before or after any other immunological veterinary medicinal product therefore needs to be made on a case by case basis.

3.9 Administration routes and dosage

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:
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 °C - 25 °C) before administration.
Administer under aseptic conditions.
Only sterile syringes and needles should be used.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No information is available.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI04AB.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 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.

5.3 Special precautions for storage

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

5.4 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.

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

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10784/003/001

8. DATE OF FIRST AUTHORISATION

16 March 2016

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

05 December 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).