INMEVA®

Suspension for injection

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

STATEMENT OF THE ACTIVE SUBSTANCE(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.

Ivory-coloured suspension.

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.

CONTRAINDICATIONS:

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

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.

TARGET SPECIES:

Sheep (ewe).

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.

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.

WITHDRAWAL PERIOD:

Zero days.

SPECIAL STORAGE PRECAUTIONS:

Keep out of the sight and reach of children.

Store and transport refrigerated (2 ºC - 8 ºC).

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.

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.

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.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED:

June 2019

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.

To be supplied only on veterinary prescription.
FOR ANIMAL TREATMENT ONLY

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

Local Representative:
HIPRA UK AND IRELAND, Ltd.
Tel: (+44) 0115 845 6486

IE only: POM Prescription Only Medicine
VPA 10846/018/001

UK only: POM-V Prescription Only Medicine
Vm 17533/4019

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135 . 17170 Amer (Girona) SPAIN
Tel. (34) 972 43 06 60. Fax (34) 972 43 06 61. hipra@hipra.com