Bovilis Bovipast RSP

Introduction

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Presentation

An aqueous suspension for subcutaneous injection. One dose (5 ml) of the vaccine contains at least 105.5 TCID50 inactivated Bovine Respiratory Syncytial virus (strain EV 908) and at least 107.3 TCID50 Parainfluenza-3- virus (strain SF-4 Reisinger), together with 9 x 109 cells inactivated Mannheimia (Pasteurella) haemolytica bacteria (serotype A1) propagated under conditions of iron restriction. Aluminium hydroxide and Quil A are included as adjuvants. Sodium timerfonate is included as a preservative.

Uses

For the active immunisation of cattle against

-Parainfluenza3 virus (PI3 virus), to reduce infections.

-Bovine Respiratory Syncytial Virus (BRSV) to reduce infection and clinical signs.

-Mannheimia (Pasteurella) haemolytica serotype A1, to reduce infection, mortality, clinical signs, lung lesions and bacterial invasion of the lung caused by serotypes A1 and A6.

Cross-reactive immunity to the A6 serotype of M. haemolytica has been demonstrated in a challenge experiment under laboratory conditions after a primary course of vaccination.

Approximately two weeks after completion of the basic immunisation programme, the humoral immune response against BRS-Virus and PI3-Virus is at its highest level. The duration of protective immunity has not been established in challenge experiments.

Dosage and administration

Vaccination dose: 5 ml by subcutaneous injection at the side of the neck.

The vaccine proved to be safe during use in pregnancy and lactation.

Basic administration:

Animals from approximately 2 weeks of age or over should receive two vaccinations separated by an interval of approximately 4 weeks.

Booster doses:

If booster doses are required, they should be given approximately 2 weeks before each period of risk (e.g. transport, introduction into a herd, change of housing).

Shake the bottle well before use.

For vaccine administration, needles of 1.5 to 2.0 mm diameter and 10 to 18 mm long are recommended. The vaccine should be brought to room temperature prior to use and injected without delay.

To avoid contamination of the vaccine and loss of activity after opening, multi-dose containers have to be used within 10 hours of first broaching the cap. Any unused product or waste material should be disposed of in accordance with national requirements.

The basic immunisation should be started in time, so that immunity has fully developed by the beginning of the period of risk. The basic immunisation of calves should be completed prior to housing or should be performed in the housing unit under quarantine. It is advisable to vaccinate all animals in a herd in order to minimise the infectious potential unless there is a contraindication. Failure to vaccinate individual animals may promote the transmission of pathogens and development of disease. The magnitude of the antibody response may be reduced by maternally derived antibodies in calves up to six weeks of age. However, according to the results of challenge experiments, significant protection against infection by BRS-Virus is still provided three weeks after the basic vaccination course, and significant protection against PI-3-Virus and Mannheimia (Pasteurella) haemolytica serotype A1 is still provided six weeks after the basic vaccination course. The results of challenge experiments in calves with maternally derived antibodies further indicate that the onset of cross-protective immunity to the A6 serotype is 2 weeks after completion of the vaccination course. Cross protective immunity is provided up to six weeks after the basic vaccination course as demonstrated by serological tests. Respiratory infections in calves are often associated with

poor hygiene. Thus, general improvements in hygiene are important to support the effect of vaccination.

Contra-indications, warnings, etc

Avoid vaccination of animals that have intercurrent disease, heavy parasitic infestation or are in poor general condition, since a satisfactory immune response will only be obtained in healthy and immuno-competent animals.

Immunisation may result in temporary swellings at the injection site (in extreme cases narrow swellings up to 10 cm long may occur). Typically, these swellings completely disappear or reduce in size to a negligible small lump within 2 to 3 weeks after vaccination, though in individual animals very small reactions can be found for up to 3 months. Additionally, a transient slight rise in body temperature, lasting a maximum of 3 days, may occur after vaccination and at the same time a slight reluctance to move may be found.

Occasional hypersensitivity reactions may occur.

Operator warnings:

In the case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Intervet's live IBR marker vaccine (where this product is authorised) in cattle from 3 weeks of age onwards. No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. 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.

Immunosuppressive drugs should generally not be used directly before or after vaccination, since a satisfactory immune response will only be obtained in immuno-competent animals.

Do not mix with any other medicinal product.

Withdrawal period

Zero days

For animal treatment only. Keep out of the reach and sight of children.

Pharmaceutical precautions

Store in a refrigerator (2°C - 8°C). Protect from light and frost.

In-use shelf life: 10 hours.

Legal category

POM-V

Packaging Quantities

50 ml bottle (10 doses).

Further information

Nil.

Marketing authorisation number

Vm 01708/4458.

GTIN (Global Trade Item No)

Bov Bovipast RSP 1x50ml:

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