

FOR ANIMAL HEALTH USE ONLY

PASTEDOLL



SUSPENSION FOR INJECTION

Dollvet

INACTIVATED BACTERIAL VACCINE AGAINST PASTURELLA MULTOCIDA AND MANNHEIMIA HAEMOLYTICA INFECTIONS

COMPOSITION:

Inactivated <i>Pasteurella multocida</i> antigen	≥ 1/40 ELISA seropositive*
Inactivated <i>Mannheimia haemolytica</i> A1 antigen and leucotoxin	≥ 1/40 ELISA seropositive*
Inactivated <i>Mannheimia haemolytica</i> A2 antigen and leucotoxin	≥ 1/40 ELISA seropositive*

*Antibody titer by ELISA of rabbit serum vaccinated with 1 sheep dose (2 ml)

Excipients

Aluminum hydroxide: 4,5 mg/ml

IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QI02AB, QI03AB, QI04AB

Pharmacotherapeutic group: Immunologics (Inactivated Bacterial Vaccine)

FIELD OF USE/INDICATIONS:

It is an inactivated bacterial vaccine formulated for proactive immunization against infections caused by *Pasteurella multocida* and *Mannheimia haemolytica* in cattle, ovine, and caprine species, commencing from the age of three weeks. Passive immunity against *Pasteurella multocida* and *Mannheimia haemolytica* diseases is expected to last up to 3 weeks in calves, lambs and kids born from pregnant animals vaccinated with Pastedoll, provided they receive colostrum. Active protective immunity is anticipated to commence 14 days post the second vaccination, providing safeguarding for a duration of 6 months.

USAGE AND DOSAGE:

The vaccine is administered subcutaneously at 2 ml in sheep and goats and 4 ml in cattle. Animals undergoing their initial vaccination should receive a subsequent dose 21 days following the primary vaccination.

Vaccinated animals should be given a single dose as re-vaccination after 6 months.

Unvaccinated pregnant animals are recommended to undergo two vaccinations, administered 6-9 weeks prior to parturition, with an interval of 21 days between doses. In vaccinated pregnant animals, a single dose of vaccination should be given 3-6 weeks before birth.

SPECIAL CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES:

Vaccination should be administered to healthy animals only. Vaccine vial should be shaken well before use. Vaccine must be equilibrated to room temperature before administration. Aseptic needles and syringes should be used in every application.

Use of Vaccine during Pregnancy, Lactation

Vaccine is safe to use during pregnancy and lactation.

ADVERSE EFFECTS:

Anaphylactic reactions may occur infrequently. In this case, symptomatic treatment should be applied. No adverse effects were reported in safety and toxicity studies conducted on both experimental animals and the intended target animals. A subset of vaccinated animals may experience pinhead-size swelling at the injection site. Temporary increase in body temperature may occur.

DRUG INTERACTIONS:

There is no information on the compatibility of this product with other vaccines. The concurrent or staggered use of this product with other products on the same day has not been substantiated for efficacy and safety.

The product should not be mixed with any other product during application.

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SYMPTOMS, MEASURES AND ANTIDOTE IN CASE OF OVERDOSE:

Being an inactive product, no overdose study has been conducted.

WITHDRAWAL PERIOD:

Zero (0) days.

CONTRAINDICATIONS:

No contraindications have been observed.

GENERAL WARNINGS:

"Keep out of the reach of children"

"Consult your veterinarian in case of unexpected effects"

PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE VACCINE AND RECOMMENDATIONS FOR VETERINARIANS:

Should inadvertent injection occur, it is advised to thoroughly clean and disinfect the affected area, and seek medical attention if deemed necessary. It should be applied by a Veterinarian or Health Technicians under the supervision of a Veterinarian.

STORAGE CONDITIONS AND SHELF LIFE:

Shelf life of the product exposed for sale: Suspension for injection 24 months.

Shelf life after opening the inner package: 6-8 hours

The suspension for injection is stored in the cold chain (at +2/8°C) and in dark environment. Vaccine should not be frozen.

WARNINGS FOR END-OF-USE DISPOSAL AND NON-TARGET SPECIES:

After the use of vaccines, any leftover material should be disposed of by boiling, incineration or soaking in a suitable disinfectant.

FORMS OF COMMERCIAL PRESENTATION:

This vaccine is available in amber glass vials with capacities of 20, 50, and 100 ml, or in white polypropylene plastic vials ranging from 50 to 250 ml and these vials are equipped with butyl plugs and aluminum caps, and contain 10, 25, 50, and 125 doses for sheep and goats packaged in individual cardboard boxes with package insert. Not all forms of packaging may be available at the same time.

DATE OF APPROVAL OF LEAFLET: 26.10.2023

T.R. DATE OF MARKETING AUTHORIZATION ISSUED BY THE MINISTRY OF
AGRICULTURE AND FORESTRY: 26.10.2023

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:

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