

FOR VETERINARY USE ONLY

CAPRIDOLL-FL



INACTIVATED VACCINE AGAINST CONTAGIOUS CAPRINE PLEUROPNEUMONIA

Dollvet

LYOPHILISATE FOR SUSPENSION FOR INJECTION

COMPOSITION:

Minimum quantities in each dose (1 ml) are as follows:

Ingredients	Quantity	Strength
Inactive <i>Mycoplasma capricolum</i> subsp. <i>capripneumoniae</i> (Mccp) F38 strain	0,15 mg/dose	Immunizing antigen
PPLO	0,22 mg/dose	Preservative
Yeast extract	0,50 mg/dose	
Glucose	0,15 mg/dose	
Inactive equine serum	15 µl/dose	

Reconstitution solvent

Ingredients	Quantity	Strength
Saponin	3 mg/dose	Inactivator/Adjuvant
Phosphate buffer solution (PBS)	Up to 1 ml	Volume Supplement

INDICATIONS:

CAPRIDOLL-FL is administered to protect goats against Contagious Caprine Pleuropneumonia. It can also be administered in pregnancy and lactation period.

CONTRAINDICATIONS:

It should not be administered to infected animals or those in incubation period.

ADVERSE REACTIONS:

In some animals, hard or soft swellings, 0,2-3 cm in diameter may be observed at the injection site. Since the vaccine contains saponin, hypersensitivity reactions may occur. In such a case, adrenaline or antihistamine preparations should be administered.

TARGET SPECIES:

Goats and kids.

DOSAGE AND METHOD AND ROUTE OF ADMINISTRATION FOR EACH SPECIES:

The vaccine is administered subcutaneously to goats and kids over 3 months of age in 1 ml to the immobile part behind the scapula.

ANIMAL SPECIES	ADMINISTRATION SITE	DOSE and VACCINATION SCHEDULE	
		1st ADMINISTRATION	2nd ADMINISTRATION (1 year later)
Goats and kids	Subcutaneous injection into the immobile part behind the scapula	1 ml / SC	1 ml / SC

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WITHDRAWAL PERIODS:

The withdrawal period after vaccination is minimum 7 days for milk and minimum 28 days for meat.

PRESENTATION:

For vaccine lyophilization: 10 ml Type I neutral glass vials with butyl stoppers for closing the vials and aluminum top caps are used for 25, 50 and 100 doses respectively. For reconstitution solvent: 25, 50 and 100 ml Type II glass or plastic bottles with butyl stoppers and aluminum top caps to seal the bottles, are used. Lyophilized vaccine vials are supplied in boxes of 10.

STORAGE CONDITIONS AND SHELF LIFE:

Stored at +2/8°C, and in the dark. Shelf life is 2 years.

WARNINGS:

Vaccines should be stored at +2/8°C and shaken well before use. Opened vials should be used within 2 hours, and necessary precautions should be taken for transportation of vaccines at storage temperature.

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

- As a first step to vaccination, the lyophilized pellet is homogenized with 2-3 ml reconstitution solvent. The content is drawn into a sterile syringe and added to the reconstitution solvent. This process repeated several times.

- The vial should be shaken well before use.
- Opened vials should be used within 2 hours. Partly used or empty vials should be disposed of as per regulated.
- Vaccines exposed to high heat or sunlight, frozen, or packaging integrity broken, should never be used.
- Animals to be vaccinated must be in good health.
- Asepsis and antiseptics principles should be followed during administration.
- During vaccination, special care should be taken not to contaminate the eyes or hands. In case of an accidental contact, the site should be cleaned with water and disinfected.
- The vaccine should only be administered by a veterinarian or a veterinary technician under the supervision of a veterinarian.

DISPOSAL OF WASTE AND UNUSED PRODUCTS:

Unused or opened but not completely used vaccines are disposed of as medical waste, according to the provisions of the applicable waste regulations.

GENERAL WARNINGS:

Keep out of reach of children.

Consult a veterinarian upon an unexpected effect.

DATE OF MARKETING AUTHORIZATION: 07.01.2019

FINAL PROSPECTUS APPROVAL DATE: 07.01.2019

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:

Dollvet Biyoteknoloji Anonim Şirketi

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NAME AND ADDRESS OF PRODUCTION SITE:

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