

Dollvet

SOLUTION FOR INJECTION

COMPOSITION:

Name and brief description of the veterinary biological product: DOLLI-SERA is a hyperimmune serum prepared by intensive immunization of cattle with Salmonella Dublin, Salmonella Typhimurium, Pasteurella multocida, Mannheimia haemolytica, Trueperella (Arcanobacter) pyogenes, Escherichia coli bacteria and Clostridium perfringens Type C β toxoid, used to protect calves, lambs and kids against septicemic, enteric and respiratory infections and to treat infected animals.

Names and strength of active substances and names and quantities of other excipients
Composition of the biological product: Minimum ratios per 1 ml are as follows:

Ingredients	Ratio	Strength
Antibody titer against Salmonella Typhimurium strain	1/320	Immunizing antbody
Antibody titer against Salmonella Dublin strain	1/320	
Antibody titer against Pasteurella multocida Type 1 strain	1/16	
Antibody titer against Mannheimia haemolytica A1 strain	1/16	
Antibody titer against Trueperella pyogenes strain	1/160	
Antibody titer against Escherichia coli 11A and EC strain*	1/960	
Antitoxin titer against Clostridium perfringens Type C β toxin	10 IU	
Buffered physiologic saline water	Up to 1 ml	Solvent
Phenol	0.4%	Stabilizer

^{*} Antibody titer against Escherichia coli K99 antigen

INDICATIONS:

DOLLI-SERA is a hyperimmune serum used to protect calves, lambs and kids against septicemic, enteric and respiratory infections of Salmonella Dublin, Salmonella Typhimurium, Pasteurella multocida, Mannheimia haemolytica, Trueperella (Arcanobacter) pyogenes, Escherichia coli bacteria and Clostridium perfringens Type C β toxin, and to treat infected animals.

CONTRAINDICATIONS:

No contraindications were found in safety studies conducted with calves, lambs, kids and experimental animals.

SIDE EFFECTS:

Rarely, hypersensitivity reactions may occur. In such a case, adrenaline or similar products should be administered.

TARGET SPECIES:

Calves, lambs and kids.

DOSAGE AND ADMINISTRATION METHOD AND ROUTE FOR EACH SPECIES:

For protection, subcutaneous injection of 5 ml to calves, and 1 ml to lambs and kids. For treatment, subcutaneous injection of 10 ml to calves, and 3 ml to lambs and kids.



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WITHDRAWAL PERIODS:

None.

PRESENTATION (TOTAL DOSES AND FILLING VOLUME):

1, 5, 10 and 20 calf doses or 5, 25, 50 and 100 lamb and kid doses respectively, in 5 ml, 25 ml, 50 ml and 100 ml amber colored glass or plastic vials in 25 ml, 50 ml and 100 ml boxes or 5x5 ml, 10x5 ml boxed/plastic travs in styrofoam.

STORAGE CONDITIONS AND SHELF LIFE:

Store at + 2/8°C, and in the dark. Shelf life is 2 years. Do not freeze.

WARNINGS:

Hyperimmune serum should be stored at +2/+8°C and in the dark. It should be shaken well before each use. Opened vials should be used within 6-8 hours, and necessary precautions should be taken to ensure the serum does not overheat.

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

In case of an accidental injury of the person administering the serum, the wound should be disinfected, and medical attention should be sought.

DISPOSAL OF WASTE AND UNUSED PRODUCTS:

Unused or opened but not completely used sera 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.

LEAFLET APPROVAL DATE: 04.12.2018

DATE OF MARKETING AUTHORIZATION: 04.12.2018

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:

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