FOR VETERINARY USE ONLY

COLIDOLL

EMULSION FOR INJECTION

Dollvet

INACTIVATED ESCHERICHIA COLI VACCINE

COMPOSITION:

Name and brief description of the veterinary biological product: COLIDOLL is an oil adjuvanted and inactivated vaccine used in pregnant cows to protect newborn calves from E. coli infections.

Names and strength of active substances and names and quantities of other excipients:
The quantities in each dose (2 ml) are as follows:

Ingredients	Quantity	Function
E.coli EC (O101: H-K99+F41+) strain	$1x10^{10}$ cfu/dose*	Antigen
E.coli 11A (O?:H-K99+:, F(Y)+) strain	$1x10^{10}$ cfu/dose*	Antigen
Oil adjuvant (Montanide ISA)	1 ml	Adjuvant
Formaldehyde (37%)	2 µl	Inactivator
Water for injection	Max. 1 ml	Volume supplement

* Colony count before inactivation

INDICATIONS:

Administered to pregnant cows to protect newborn calves against diarrhea caused by *Escherichia coli*.

CONTRAINDICATIONS:

None.

SIDE EFFECTS:

None.

TARGET SPECIES:

Pregnant cows.

DOSAGE, METHOD AND ROUTE OF ADMINISTRATION FOR EACH SPECIES:

- The vaccine is administered with subcutaneous injection of 2 ml into the immobile area behind the shoulder.
- The administration dose is 2 ml.
- Should be administered 4-6 weeks before calving.

WITHDRAWAL PERIODS:

Withdrawal period is 0 days.

PRESENTATION:

The vaccines are packaged as boxed in 6 ml amber colored Type I glass vials containing 1 and 2 doses, or as unboxed but placed in 10-unit plastic trays wrapped in styrofoam; and in 10, 20, 50 and 100 ml amber colored Type II glass vials containing 5, 10 (boxed/unboxed), 25 and 50 doses.
Not all forms of packaging may be placed on the market. The vials are placed on the market as boxed in 50 or 100-unit styrofoam trays which contain the same number of leaflets.

STORAGE CONDITIONS AND SHELF LIFE:

Stored at +2/8ºC, and in the dark. Do not freeze. Shelf life is 2 years.

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WARNINGS:

- The vaccine is administered to healthy pregnant cows.
- The vaccine is stored in cold chain conditions.
- Opened vials should be used within the same day. Partly used or empty vials should be disposed of as per regulated.
- Frozen vaccines and those stored out of cold chain conditions should not be used.
- The vaccine is homogenized by shaking well before and during use.
- Asepsis and antisepsis principles should be followed during administration.
- In rare cases of anaphylactic shock developing shortly after vaccination in susceptible animals, adrenergic and antihistaminic preparations should be administered.
- The vaccine should only be administered by a veterinarian or a veterinary technician under the supervision of a veterinarian.

DISPOSAL PRECAUTIONS FOR WASTE/UNUSED PRODUCTS:

Vaccines not meeting administration standards (exposed to high heat or sunlight, frozen, packaging integrity broken, or lacking cap, stopper or label authenticity) are disposed of in compliance with the national medical waste regulations.

GENERAL WARNINGS:

Keep out of reach of children.
Consult a veterinarian upon an unexpected effect.

FINAL LEAFLET APPROVAL DATE: 14.02.2019

DATE OF MARKETING AUTHORIZATION ISSUED BY MINISTRY OF AGRICULTURE AND FORESTRY: 22.12.2011

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:

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NAME AND ADDRESS OF PRODUCTION SITE:

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