





INACTIVE ESCHERICHIA COLI VACCINE

COMPOSITION:

Name and brief description of the veterinary biological product; COLİDOLL is an oil-adjuvant inactive vaccine used in pregnant cows to protect newborn calves from E. coli infections.

Name and power of active substances, and auxiliary substances, if it exist: The dose content of the vaccine (2 ml) is as follows.

Components	Amount	Function
E.coli EC (0101: H-K99 F41) strain	1x10 ¹⁰ cfu/ dose*	Antigen
E.coli 11A (0?: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	Up to 1 ml	Volume complement

^{*} Colony count before inactivation

INDICATIONS:

It is administered to pregnant cows in order to protect newborn calves against diarrhea caused by Escherichia coli.

CONTRAINDICATIONS:

It has no contraindications

ADVERSE EFFECTS:

It has no adverse effects.

TARGET SPECIES:

Pregnant cows.

METHOD OF ADMINISTRATION AND DOSE:

The vaccine is administered to the immobile areas behind the shoulders subcutaneously. The administration dose is 2 ml.

It should be administered 4-6 weeks before birth.

WITHDRAWAL PERIOD FOR ANIMAL ORIGIN PRODUCTS:

Withdrawal period for animal origin products is 0 days.

NLY USED FOR ANIMAL HEALTH



INJECTABLE EMULSION



INACTIVE ESCHERICHIA COLI VACCINE

PRESENTATION:

The vaccine is packaged as 1 dose and 2 doses in 6 ml of Type I amber colored glass vials, unboxed or packaged each 10 vials in plastic viols in Styrofoam, .10, 20, 50 and 100 ml type II amber colored glass vials, corresponding 5 doses, 10 doses (boxed/unboxed in Styrofoam), 25 doses and 50 doses, respectively. Not all packaging forms could be in the market. The vaccine Styrofoam containing 50 and 100 ml bottles, are supplied with prospectus corresponding the vaccine bottles quantity.

STORAGE CONDITIONS AND SHELF LIFE:

It is stored in the dark at 2 / 8°C. Do not freeze. Its shelf life is 2 years.

WARNINGS:

The vaccine is applied to healthy and pregnant cows. The vaccine is stored in the cold chain. Each opened vaccine vial should be used within the same day. Any remain or empty vaccine vials should be disposed of properly. Vaccines that are frozen and out of the cold chain are not used. Homogenization is achieved by shaking the vaccine before and during use. Asepsis and antisepsis should be taken into consideration in vaccine administrations. In rare cases, adrenergic and antihistamine preparations should be used against anaphylactic shocks that may occur shortly after vaccination in susceptible animals.

It is applied only by veterinarians or health technicians under the supervision of veterinarians.

DISPOSAL OF WASTE AND UNUSED PRODUCTS:

Vaccines that do not meet the conditions of use (exposed to high temperatures or sunlight, frozen, lost its packaging integrity, and of which caps, stoppers or labels have lost their originality) are disposed in accordance with national medical waste regulations.

[&]quot;In case of an unexpected effect, consult the veterinarian"



THE MARKETING AUTHORIZATION ISSUED BY MINISTRY OF AGRICULTURE AND FORESTRY, DATE

AND NUMBER : 22.12.2011

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:

Dollvet Veteriner Aşı İlaç Biyolojik Madde Üretim Sanayi ve Ticaret A.Ş.

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NAME AND ADDRESS OF THE PLACE OF PRODUCTION:

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[&]quot;Keep out of reach of children"