

**LYOPHILISATE FOR SUSPENSION FOR INJECTION AND SOLVENT****PHARMACEUTICAL FORM:**

Suspension for injection consisting of lyophilized pellet and reconstitution solvent

NAMES AND STRENGTH OF ACTIVE SUBSTANCES AND NAMES AND QUANTITIES OF OTHER EXCIPIENTS VACCINE COMPOSITION:

Minimum quantities in each dose (ml) are as follows.

Ingredients	Quantity
Attenuated Trichophyton verrucosum culture	3,75x10 ⁶ - 18,75x10 ⁶ cfu/ml
Sucrose	1.875-7.5 mg/ml
Gelatine	1.25-5 mg/ml
NaCl	2.285-2.885 mg/ml
Sodium chloride (NaCl)	8.50 mg/ml
Potassium chloride (KCl)	0.21 mg/ml
Disodium phosphate dodecahydrate (Na ₂ HPO ₄ ·12H ₂ O)	2.40 mg/ml
Potassium dihydrogen phosphate (KH ₂ PO ₄)	0.21 mg/ml
Water for injection as supplement	1 ml

INDICATIONS:

The vaccine is used for protective and therapeutic purposes in order to prevent and control trichophytosis infection in cattle.

CONTRAINDICATIONS:

The vaccine should not be administered to animals with high fever, or weak and in a poor condition, and to those in herds or farms where other severe infections occur.

SIDE EFFECTS:

A lump, 10-20 mm in diameter may appear at the injection site, which then disappears within a few weeks. 14 days after the second vaccination, a scab of the same size (10-20 mm in diameter) as the trichophytosis lesions may appear at the injection site, which then falls off within two to three weeks.

TARGET SPECIES:

Cattle

DOSAGE AND METHOD AND ROUTE OF ADMINISTRATION FOR EACH SPECIES:

It is administered by intramuscular injection of 2 ml to calves up to 3 months, and 4 ml to animals older than 3 months for preventive and treatment purposes. Animals are re-vaccinated with the same dose 10-14 days later than the first administration. Symptoms of treatment are observed 20-25 days after the second dose: the scab becomes thinner, separates from the skin and hair grows again.

WITHDRAWAL PERIODS:

The withdrawal period after vaccination is 14 days for meat and 0 days for milk.

PRESENTATION:

Type I glass vials containing 1 dose of lyophilized powder with 4 ml reconstitution solvent in 1-unit cardboard boxes,
 Type I glass vials containing 1 dose of lyophilized powder with 4 ml reconstitution solvent either in 5x1 dose boxes or placed in plastic trays in styrofoam, Type I glass vials containing 2 doses of lyophilized powder with 8 ml reconstitution solvent in 5-unit cardboard boxes,
 Type I glass vials containing 5 doses of lyophilized powder with 20 ml reconstitution solvent in 1-unit cardboard boxes,
 Type I glass vials containing 10 doses of lyophilized powder with 40 ml reconstitution solvent in 1-unit cardboard boxes,
 Type I glass vials containing 20 doses of lyophilized powder with 80 ml reconstitution solvent in 1unit cardboard boxes.

FOR VETERINARY USE ONLY

TRICHODOLL



Dollvet

LYOPHILIZED LIVE VACCINE AGAINST TRICHOPHYTON VERRUCOSUM INFECTIONS

LYOPHILISATE FOR SUSPENSION FOR INJECTION AND SOLVENT

STORAGE CONDITIONS AND SHELF LIFE:

Stored at +2/8°C, and in the dark. According to real time stability studies, shelf life is 36 months.

WARNINGS:

The vaccine should not be administered to animals with high fever, or weak and in a poor condition, and to those in herds or farms where other severe infections occur. It should also not be administered to animals treated parenterally with anti-mycotic or immunosuppressive drugs.

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

The lyophilized vaccine is brought to room temperature before use, mixed thoroughly with the reconstitution solvent and administered intramuscularly in accordance with asepsis principles and the dose indicated in the leaflet.

The vaccine should be stored at +2/8°C, and in a dry and dark place.

The person administering the vaccine should take extreme care during injection, wear rubber gloves and avoid skin contact with the vaccine. The administration site should be cleaned with ethyl alcohol or a cationic disinfectant. The injector and needle used in vaccination should not be left in the barn after injection, but should be disposed of after inactivation with chemicals (1 hour in 37% formaldehyde or 4 hours in 1% peracetic acid) or heating (for 2 hours at 100°C).

The opened and reconstituted vaccine should be used within 2 hours. The remaining unused vaccine should be inactivated by heating for 2 hours at 100°C.

DISPOSAL OF WASTE AND UNUSED PRODUCTS:

Vaccines to be disposed of must first be heated at 100°C for 2 hours or inactivated with chemicals (for 4 hours in 2% ajatin solution or 1% peracetic acid).

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

LEAFLET APPROVAL DATE: 26.12.2013

DATE OF MARKETING AUTHORIZATION ISSUED BY MINISTRY OF AGRICULTURE AND FORESTRY: 26.12.2013

NAME AND ADDRESS OF MARKETING AUTHORIZATION HOLDER:

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