

TRICHOBEN AV

Lyophilisate with solvent for injection suspension for cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Biovet, a. s., Komenského 212,
683 23 Ivanovice na Hané, Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT TRICHOBEN AV

Lyophilisate with solvent for injection suspension for cattle

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Contents per 1 ml:

A) Lyophilisate

Active substance:

Trichophyton verrucosum avirulentum strain TV-M-310 min. 3.125×10^6 CFU, max. 18.75×10^6 CFU

Excipients:

0.8% sodium chloride solution
Lyophilisation medium

B) Diluent

Diluent A

1 ml

4. INDICATION(S)

For active immunisation of cattle for reduction of clinical signs of dermatophytoses due to *Trichophyton verrucosum* for prophylactic vaccination and for therapeutic use. Immunity is created within 1 month after revaccination and it persists at least one year.

5. CONTRAINDICATIONS

During vaccination and revaccination, it is necessary to avoid administration of the preparation to the same site (or close to it). Due to that, it is strictly contraindicated to administer the preparation during vaccination and revaccination to the same half of the body. Performing other than immunoprophylactic treatment during 10 days prior the first vaccination up to 20 days upon the second vaccination; or applying peroral preparations with antimicrobial effects to calves and placing vaccinated animals among any cattle infested with trichophytosis. If it is necessary to treat calves with antibiotic preparations during vaccination against trichophytosis, it is possible

to use penicillin, streptomycin, tylosine, tetracycline or sulphonamide without any risk of significant impairment of immunity against trichophytosis.

6. ADVERSE REACTIONS

A general anaphylactoid reaction can very rarely (less than 1 animal in 10000 animals) occur, usually within two hours after the administration of the vaccine. Use anti-histamine drugs (adrenalin, calcium) immediately in case of an anaphylactoid reaction.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1000 animals)
- rare (more than 1 but less than 10 animals in 10000 animals)
- very rare (less than 1 animal in 10000 animals, including isolated reports).

7. TARGET SPECIES

Cattle from the age of one day.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage:

Prophylactic and therapeutic:

- calves from the age of one day till the age of three months 2×2 ml
- cattle over the age of three months 2×4 ml

Interval between vaccination and revaccination is 5 – 14 days.

Method of administration:

Intramuscularly in the lumbar and/or gluteal region. Vaccination and re-vaccination must be performed always to the opposite half of the body. We recommended performance of vaccination into the left half of the body; revaccination should be made into the right half of the body.

9. ADVICE ON CORRECT ADMINISTRATION

Lyophilisate is diluted with Diluent A before use.

Reconstituted vaccine:

a milky suspension with grey-brown sediment. When thoroughly shaken, the sediment disseminates evenly in the suspension. Use rubber gloves when performing the vaccination.

10. WITHDRAWAL PERIOD

Meat – 14 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep and transfer refrigerated ($2^{\circ}\text{C} - 8^{\circ}\text{C}$). Do not freeze.

Protect from light.

Keep out of the reach of children.

Do not use this veterinary medicine after the expiry date stated on the package.

Shelf life after reconstitution according to the instructions of use: 2 hours.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

Latent disease could be triggered during vaccination of animals in the incubation period of the disease. The clinical condition is temporarily worse, but trichophytic changes on skin in the animal gradually subside without any therapeutic intervention. All animals in the stables must be vaccinated. Vaccination is also necessary after storing all newly stopped 1 – 2 month calves and animals transferred, since *Trichophyton verrucosum* is very resistant and survives in the environment for 6 – 8 years.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Use rubber gloves during vaccination.

Use during pregnancy, lactation:

May be used during pregnancy.

Interaction with other medicinal products

and other forms of interaction:

Oral treatment with anti-mycotic agents is not recommended together with vaccination. No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Overdose:

Tenfold vaccine dose has no adverse effects to target animals.

Incompatibilities:

Do not mix with any other veterinary medicinal product, except diluent or other component supplied for use with the veterinary medicinal product.

Vaccinating animals in the incubation stage of the disease may invoke a latent form of the disease. The clinical status will get worse, but in most cases, the animals will progressively lose the trichophytic changes on skin without any other treatment.

Every housed animal in the stock must be vaccinated. Vaccination is also necessary after storing all newly stopped 1 – 2 month calves and animals transferred, since *Trichophyton verrucosum* is very resistant and survives in the environment for 6 – 8 years.

13. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED PREPARATION OR WASTE MATERIAL

Inactivate any used vial and aid.

These items may not be left in the stable. It is appropriate to use 2% Ajatin solution, 1% peracetic acid solution (for a period of 4 hours) for inactivation or it is possible to perform heat inactivation (100°C , 2 hours).

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2014

15. OTHER INFORMATION

Pharmaceutical form

Lyophilisate with solvent for injection suspension.

Interaction with other medicinal products

and other forms of interaction
Oral treatment with antimicrobial agents is not recommended together with vaccination. No information regarding the safety and efficacy of this vaccine if administered simultaneously with another veterinary medicinal product is available. Decision on whether to use the product before/after the use of any other veterinary medicinal product should only be made on a case-to-case basis.

Packaging size

The box of 5 vials of lyophilisate and 5 vials of 10 ml of diluent. The box of 1 vial of lyophilisate and 1 vial of 40 ml of diluent. The box of 1 vial of lyophilisate and 1 vial of 80 ml of diluent.

Not all pack sizes may be marketed.

For animal treatment only.

To be supplied only on veterinary prescription.

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