BIOVETA, a. s., Komenského 212, 683 23 Ivanovice na Hané, Czech Republic,
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PACKAGE LEAFLET

TRICHOBEN AV

Lyophilisate and solvent for suspension for injection for cattle

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

TRICHOBEN AV
Lyophilisate and solvent for suspension for injection for cattle

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Composition in 1 ml:

A) Lyophilisate
Active substance:
Trichophyton verrucosum avirulentum strain TV-M-310 min. 3.125 x 10^6 CFU, max. 18.75 x 10^6 CFU
Excipients:
0.8% sodium chloride solution
Lyophilisation medium

B) Diluent
Diluent A 1 ml

The visual appearance:
Lyophilisate: white to brown colour, spongy structure.
Diluent A: colourless, pellucid solution without sediment.

4. INDICATIONS

For active immunisation of cattle to reduce clinical signs of dermatophytosis caused by *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.
Performance of other immunoprophylactic procedures in the period of 10 days prior to the first vaccination until 20 days after the second vaccination or administration of oral preparations with antimycotic effects to calves and placing the vaccinated animals among cattle affected with trichophytosis are contraindicated. 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 10.000 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 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

7. TARGET SPECIES
Cattle from the age of one day.

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

Dosage:
Prophylactic and therapeutic:
- calves from the age of one day till the age of three months 2 x 2 ml
- cattle over the age of three months 2 x 4 ml

Interval between vaccination and revaccination is 5 – 14 days.

Method of administration:
Intramuscular to the lumbar or gluteal region. Vaccination and revaccination 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 during vaccination.

10. WITHDRAWAL PERIOD
Meat - 14 days.

11. SPECIAL STORAGE PRECAUTIONS
Store and transport refrigerated (2 °C – 8 °C). Do not freeze.
Protect from light.
Keep out of the sight and reach of children.

Shelf-life after dilution or reconstitution according to directions: 2 hours

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. SPECIAL WARNINGS

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

Used vials and devices need to be inactivated; they cannot 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

15. OTHER INFORMATION

Pharmaceutical form
Lyophilisate and solvent for suspension for injection.

Package size
Box contained 5 vials with lyophilisate and 5 vials of 10 ml solvent
Box contained 1 vial with lyophilisate and 1 vial of 40 ml solvent
Box contained 1 vial with lyophilisate and 1 vial of 80 ml solvent

Not all pack sizes may be marketed.

For animal treatment only. To be supplied only on veterinary prescription.

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