SUMMARY OF PRODUCT CHARACTERISTICS, LABELLING, PACKAGE LEAFLET

English version

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TRICHOBEN AV
Lyophilisate and solvent for suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition in 1 ml:

A) Lyophilisate
Active substance:
Trichophyton verrucosum avirulentum strain TV-M-310 min. 3.125×10^6CFU, max. 18.75×10^6CFU
Excipients:

0.8% sodium chloride solution

Lyophilisation medium

B) Diluent
Diluent A 1 ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Cattle from the age of one day.

4.2 Indications for use, specifying the target species

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.

4.3 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.

4.4 Special warnings

Lyophilisate is diluted prior to usage with Diluent A. Vaccine must therefore be used within two hours after reconstitution.

4.5 Special precautions for use

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.

4.6 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).

4.7 Use during pregnancy, lactation

May be used during pregnancy.

4.8 Interaction with other medicinal products

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.

4.9 Amounts to be administered and administration route

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.
Reconstituted vaccine: a milky suspension with grey-brown sediment. When thoroughly shaken, the sediment disseminates evenly in the suspension.

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.

4.10 Overdose

Tenfold vaccine dose has no adverse effects to target animals.

4.11 Withdrawal periods

Meat - 14 days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: 97 Veterinary immunopreparations
ATCvet code: QI02AP01

For stimulation of active immunity against dermatophytosis caused by dermatophyte *Trichophyton verrucosum.*

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

A) Lyophilisate
Natrii chloridum
Gelatina pro bacto
Saccharum
B) Diluent A
Natrii chloridum
Kalii chloridum
Dinatrii phosphas dodecahydricus
Kalii dihydrogenphosphas
Aqua pro iniectione

6.2 Incompatibilities

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

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years
Shelf-life after dilution or reconstitution according to directions: 2 hours

6.4. Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze. Protect from light.

6.5 Nature and composition of immediate packaging

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

Type I glass vial contained lyophilisate closed with bromobutyl stopper and aluminium seal.
Type I/II glass vials contained solvent closed with chlorobutyl stopper and aluminium seal.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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).

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

To be completed by local affiliate.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be completed by local affiliate.

10 DATE OF REVISION OF THE TEXT

To be completed by local affiliate.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.