SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TRICHOBEN
Lyophilisate and solvent for preparation of injection suspension for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition – 1 ml:

A) Lyophilizate
Active substance:
Trichophyton verrucosum – min. 3,125 x 10^6 CFU, max. 18,75 x 10^6 CFU
Excipients:
0,8% solutio natrii chloridi
Nutrimentum moderans (pro lyophilisatione TRICHO)

B) Solvent
Diluent A 1 ml

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for preparation of injection suspension for cattle

4. CLINICAL PARTICULARS

4.1 Target species

Cattle from one day of age.

4.2 Indications for use, specifying the target species

Both the prevention and treatment of bovine trichophytosis.

4.3 Contraindications

Other immuno-prophylactic interventions are contraindicated during the period from 10 days before the first vaccination till 20 days after the second (third) vaccination; no oral preparations having the antimycotic effects shall be also applied to calves; the vaccinated animals shall not be kept together with other cattle infected by trichophytosis. Penicillin, streptomycin, tylosine, tetracycline or sufonamide may be used when calves should be treated with antibiotic preparations during the vaccination against trichophytosis in order to avoid the risk that the immunity against trichophytosis being formed would be affected significantly.

4.4 Special warnings

Lyophilizate shall be dissolved with Diluent A enclosed before use.
The vaccine shall be consumed within two hours since its dissolution.

4.5 Special precautions for use

Special precautions for use in animals
The latent disease can be provoked when animals being in the incubation stage of the disease are vaccinated. Their clinical conditions could impair temporary but the trichophytic changes apparent on skin disappear gradually spontaneously.
All animals kept in the breeding shall be vaccinated. Analogously all newly included calves or newly delivered animals shall be additionally vaccinated because Trichophyton verrucosum is very resistant and can survive in the animal's environment for 6 – 8 years.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Rubber gloves should be used during the vaccination.

4.6 Adverse reactions (frequency and seriousness)
Total anaphylactoid response can occur rarely, obviously within two hours after the vaccine application. If the anaphylactoid response occurs the preparations with antihistamine effect (adrenalin, calcium) should be immediately applied. Thin surface crust 10 mm – 20 mm in diameter that drops off spontaneously within 2 – 4 weeks can appear at the application spot 10 – 14 days after the vaccination.

4.7 Use during pregnancy, lactation
Can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction
Parenteral or oral treatment with antimycotic preparations should not be performed simultaneously with the vaccination.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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 at the lumbar or gluteal region. Vaccination and revaccination should be performed into the left and the right part of a body, respectively.

Dosage:
Prophylactic and therapeutic:
- Calves aged one day up to three months: 2 x 2 ml
- Cattle older than three months: 2 x 4 ml

The interval between the vaccination and the revaccination should be 5 – 14 days.

Another (the third) revaccination can be performed 2 – 4 weeks after the revaccination in the animals affected heavily with trichophytic changes and also in cachectic animals.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary
The ten-fold vaccine dose has no side effects to the target animals.

4.11 Withdrawal periods
Meat: 14 days

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Veterinaria immunopraeparata
ATCvet code: QI02AP01
Immunity of the cellular type and partially of the humoral type is induced in the immunized animals. Immunity onset is apparent within 1 month after the revaccination and lasts at least 5 years.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

A) Lyophilizate
Sodium chloride
Gelatine
Sucrose
B) Solvent
Sodium chloride
Potassium chloride
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Water for injections

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

3 years
The vaccine shall be consumed within 2 hours since its dissolution.

6.4. Special precautions for storage

Store and transport refrigerated (2°C – 8°C).
Protect from frost.
Protect from light.

6.5 Nature and composition of immediate packaging

Vaccine is supplied in the freeze-dried state in 10-ml vials, hydrolytic quality I, sealed with rubber stopper and aluminium cap.
Relevant amount of Diluent A is supplied in cartoon/plastic box together with the vaccine.
Diluent A is supplied in vials of hydrolytic quality I or II, sealed with rubber stopper and aluminium cap: presentation 10 ml in 10-ml vial, presentation 40 ml in 50-ml vial, presentation 80 ml in 100-ml vial.

Package size:
plastic box 5 x 10 ml,
carton box 1 x 40 ml, 1 x 80 ml
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

The vials and all means used shall be inactivated; never let them in a shed. 2-% Ajatin solution, 1-% peracetic acid solution (for 4 hours) and/or inactivation by heat (100 ºC, 2 hours) are recommended for inactivation.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

97/200/92-C

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

5.3.1992, 28.3.2002, 13.12.2006

10 DATE OF REVISION OF THE TEXT
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