SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TRICHOVEC**,** Lyophilisate and solvent for suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of reconstituted vaccine contains

Active substance:
Trichophyton verrucosum Bodin 1902: min. 3.125 x 10^6 CFU, max. 18.75 x 10^6 CFU*

*CFU = Colony Forming Units

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Brownish grey lyophilisate and solvent for suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

For the prophylactic immunization of cattle from 1 day of age onwards to reduce skin lesions caused by *T. verrucosum* and to prevent shedding of *T. verrucosum* from the site of infection.
For the therapeutic immunisation of cattle from 1 day of age onwards. Therapeutic use of the vaccine has been demonstrated when the vaccination schedule is completed within 4 weeks after establishment of the infection. It has been shown that this shortens the duration of skin lesions caused by *T. verrucosum* and reduce the duration of shedding of *T. verrucosum* from the site of infection. The therapeutic effect at longer intervals between infection and vaccination has not been demonstrated.

Onset of prophylactic immunity: 4 weeks.
Onset of therapeutic immunity: 4 weeks.
Duration of Immunity: 5 years.

4.3 Contraindications

None

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals
Latent disease can be provoked when animals are vaccinated for prophylactic use while in the incubation stage of the disease. Their clinical condition could temporarily be impaired and trichophytic changes may appear on the skin. These disappear spontaneously.

All animals on the farm shall be vaccinated. Newly arrived or newly born calves shall also be 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 preparation of the vaccine and during vaccination to avoid accidental dermal exposure.

People with a known impaired immune system or using immunosuppressive medication should not handle this vaccine.

4.6 Adverse reactions (frequency and seriousness)

A scab 10 mm – 20 mm in diameter that drops off spontaneously within 2 – 4 weeks appears very commonly at the site of application 10 – 14 days after the vaccination and is an indicator for take of the vaccination.
An anaphylactic reaction may occur in rare cases, within two hours after the vaccine application. If an anaphylactic reaction occurs, a preparation with antihistamine effect (adrenalin, calcium) should be applied immediately.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

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. 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

Lyophilizate is reconstituted with Diluent A as follows:

The stopper surface shall be disinfected.

For the 10 ml presentation (1 ml lyophilizate to be reconstituted with 10 ml Diluent A) the Diluent A is transferred into the vial containing the lyophilized vaccine (a sterile needle is applied through the stopper). The vaccine is shaken well and after reconstitution this constitutes the ready-to-use vaccine.

For the 40 and 80 ml presentation (4 or 8 ml lyophilizate to be reconstituted with 40 or 80 ml Diluent A respectively), part of Diluent A (approximately 10 ml) is transferred into the vial containing the lyophilized vaccine (a sterile needle is applied through the stopper). The reconstituted vaccine must be shaken well and transferred to the vial with the rest of Diluent A. The ready to use vaccine must be shaken well before application.

Please note that the reconstituted vaccine may contain fine unshakeable particles as remnants of production. This is of no consequence.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In addition to the adverse reactions already mentioned under 4.6, after a ten-fold overdose oedematous swellings up to a size of 2 cm in diameter might occur which disappears within 14 days. In addition the rectal temperature might increase up to 1.2 °C around day 10 post administration.

4.11 Withdrawal period(s)

Meat: 14 days

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live fungal vaccines
ATCvet code: QI02AP01

Immunity of the cellular type and partially of the humoral type is induced in the immunized animals.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

A) Lyophilizate
Sodium chloride
Gelatin
Sucrose

B) Solvent
Sodium chloride
Potassium chloride
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after reconstitution according to directions: use immediately

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 or Flip off
Corresponding amounts of Diluent A is supplied in carton 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:
5 x 10 ml, 1 x 40 ml, 1 x 80 ml (after reconstitution)
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 other materials used shall be inactivated by exposing them for 4 hours to a 2% Ajatin solution or a 1% Persteril or exposing them to heat (boiling at 100 ºC) for 2 hours.

7. MARKETING AUTHORISATION HOLDER

Animal Health Distributors Limited
Tullow Industrial Estate
Bunclody Road
Tullow
Carlow
R93WOD8
Ireland

8. MARKETING AUTHORISATION NUMBER

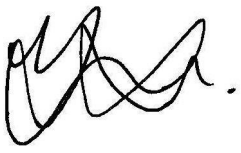
Vm 51609/5000

9. DATE OF FIRST AUTHORISATION

13 June 2023

10. DATE OF REVISION OF THE TEXT

June 2023



Approved: 13 June 2023