1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TRICHOVEC, lyophilisate and solvent for suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1.0 ml of vaccine contains:

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

**CFU = Colony Forming Units*

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Sodium chloride
Gelatine
Sucrose
Solvent:
Sodium chloride
Potassium chloride
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Water for injections

Brownish grey lyophilisate and solvent for suspension for injection.

3. CLINICAL INFORMATION

3.1 Target species

Cattle

3.2 Indications for use for each target species

For the prophylactic immunisation 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.

3.3 Contraindications

None.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species

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 should be vaccinated. Newly arrived or newly born calves should 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.

Immunocompromised persons are advised to avoid contact with the vaccine

3.6 Adverse events

Very common (more than 1 in 10 animals treated)	Scab formation at the injection site[1]
Rare (1 to 10 animals / 10,000 animals treated):	An anaphylactic reaction may occur within two hours after the vaccine application[2].

[1] A scab (10 mm – 20 mm in diameter) that drops off spontaneously within 2 – 4 weeks appears at the site of application 10 – 14 days after the vaccination and is an indicator for take of the vaccination.

[2] If a hypersensitivity reaction occurs, appropriate treatment should be administered without delay. Such reactions may evolve to a more severe condition which may be life-threatening.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

3.8 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.

3.9 Administration route and dosage

Intramuscular at the lumbar or gluteal region. Vaccination and revaccination should be performed into the left and the right part of a body, respectively.

Lyophilisate is reconstituted with Diluent A as follows:

The stopper surface should be disinfected.

For the 10 ml presentation (1 ml lyophilisate to be reconstituted with 10 ml Diluent A) the Diluent A is transferred into the vial containing the lyophilised 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 lyophilisate 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 lyophilised 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.

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.

3.10 Symptoms of overdose (and where applicable emergency procedures and antidotes)

In addition to the adverse reactions already mentioned under 3.6, 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal period(s)

Meat: 14 days

4. IMMUNOLOGICAL INFORMATION

4.1 ATC vet code: QI02AP01

Live fungal vaccines; trichophyton

To stimulate active immunity against ringworm in cattle caused by *Trichophyton verrucosum*.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities
Do not mix with any other veterinary medicinal product.

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

5.3. Special precautions for storage

Keep the containers in the outer carton.
Store and transport refrigerated (2 °C – 8 °C).
Protect from frost.
Protect from light.

5.4 Nature and composition of immediate packaging

Type I glass bottle containing lyophilisate and type I or II glass bottle containing 10 ml, 40 ml or 80 ml Diluent A, both closed with rubber stopper and sealed with an aluminium cap.

Plastic box containing 5 bottles of lyophilisate and 5 bottles of 10 ml of Diluent A

Carton box containing 1 bottle of lyophilisate and 1 bottle of 40 ml of Diluent A
Carton box containing 1 bottle of lyophilisate and 1 bottle of 80 ml of Diluent A

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. MARKETING AUTHORISATION HOLDER

Animal Health Distributors Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22715/006/001

8. DATE OF FIRST AUTHORISATION

11/04/2025

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

31/01/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Prescription Only Medicine Exempt (POM(E))

Detailed information on this veterinary medicinal product is available in the Union Product Database *(https://medicines.health.europa.eu/veterinary)*