1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TRICHOLOR
Live vaccine against trichophytosis,
Lyophilisate and solvent for solution for injection, for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1.0 mL resuspended vaccine contains:

Active substance:

live microconidia of attenuated *Trichophyton verrucosum* cultures,
strain LTF 130 min. 2 x 10^7 up to max. 6 x 10^7

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Sucrose
Gelatin
Solvent:
Sodium chloride
Water for injections

Yellowish lyophilisate
Clear, colourless solvent

3. CLINICAL INFORMATION

3.1 Target species

Cattle

3.2 Indications for use for each target species

For prophylactic and therapeutic treatment against trichophytosis caused by *Trichophyton verrucosum*, in cattle from one day of age.

Onset of immunity: Immunity develops fully within 4 weeks after the 2nd injection.
Duration of immunity: at least 2 years.

3.3 Contraindications

Do not use in
- animals with an insufficient development status,
- animals treated with fungicidal or fungistatic agents,
- severely stressed animals (stressful situations).

3.4 Special warnings

Vaccinate healthy animals only.
The clinical outbreak of trichophytosis in animals already in the incubation phase at the time of vaccination cannot be reliably prevented in every case. However, this does not have any negative effect on the healing process.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The use of gloves during vaccination is recommended.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: cattle

Very common (>1 animal / 10 animals treated):	Application site scabs (forming 10-15 days after the second injection and healing without treatment within 20-25 days)
Uncommon (1 to 10 animals / 1,000 animals treated):	Application site swelling (reversible)
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic shock

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 also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

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.
In particular, concomitant use of preparations with an antifungal effect is contraindicated before, during and after application of the vaccine, because they negatively affect the efficacy of the vaccine.

3.9 Administration routes and dosage

For intramuscular injection.

Prophylaxis:
Calves up to 4 months old 1.0 mL
Calves/cattle aged 4 months and older 2.0 mL
The vaccine is administered twice intramuscularly at an interval of 10-14 days.

Therapeutic use:
Calves up to 4 months old 2.0 mL
Calves/cattle aged 4 months and older 4.0 mL
The vaccine is administered twice intramuscularly at an interval of 10-14 days; a third injection at the same dose may be required 10 days after the second injection.

Instructions for correct administration:
To reconstitute the vaccine, about 5 mL of the solvent is transferred into the small bottle with the lyophilisate using a syringe. To dissolve the vaccine, it is gently shaken and then the dissolved vaccine is transferred to the bottle with the solvent. To rinse the lyophilisate bottle, about 5 mL of the reconstituted vaccine is removed and added to the lyophilisate bottle. Shake the bottle. Then, extract the contents and transfer them back into the bottle with the solvent. Use sterile syringes and needles.
The vaccine should be shaken prior to use.

Appearance after reconstitution: white to yellowish turbid liquid.

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

Testing of the vaccine at 10 times the recommended dose revealed no adverse reactions other than listed under 3.6.

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 periods

Meat and offal: 7 days
Milk: zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI 02 A P01.

Pharmacotherapeutic group: Vaccine for cattle, Live fungal vaccine, Trichophyton
In infected herds, herd immunisations at therapeutic doses lead to healing in clinically diseased animals. As a result of the vaccination, the chain of trichophytosis infection is interrupted and immunity over several years, in many cases for life, develops.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except solvent recommended for use with the veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months
Shelf life after reconstitution according to directions: 2 hours

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Protect from light.

5.4 Nature and composition of immediate packaging

Lyophilisate: 10 mL and 20 mL glass bottles
Glass type I according to EP

Solvent: 10 mL, 25 mL and 50 mL glass bottles
Glass type I and glass type II according to EP

The bottles are closed with a bromobutyl rubber stopper and an aluminium crimp cap.

Authorised pack sizes:
Bottle with 10 vaccine doses for calves / 5 vaccine doses for cattle, together with 10 mL solvent for resuspension

Bottle with 20 vaccine doses for calves / 10 vaccine doses for cattle, together with 20 mL solvent for resuspension

Bottle with 40 vaccine doses for calves / 20 vaccine doses for cattle, together with 40 mL solvent for resuspension

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

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. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally.

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: <{DD/MM/YYYY}><{DD month YYYY}>
To be completed nationally.

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

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database.