PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. 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

Yellowish lyophilisate
Clear, colourless solvent

3. Target species

Cattle

4. Indications for use

For prophylactic and therapeutic treatment against trichophytosis caused by T*richophyton 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.

5. Contraindications

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

6. Special warnings

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.

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

Pregnancy and lactation:

Can be used during pregnancy and lactation.

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.

Overdose:

Testing of the vaccine at 10 times the recommended dose revealed no adverse reactions other than listed under the point "Adverse events".

Special restrictions for use and special conditions for use:

Not applicable

Major incompatibilities:

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

7. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

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

9. Advise on correct administration

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.

10. Withdrawal periods

Meat and offal: 7 days
Milk: zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp.

Shelf life after reconstitution according to directions: 2 hours.

12. Special precautions for disposal

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 applicable national collection systems.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

MA number:

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.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

To be completed nationally

Manufacturer responsible for batch release:

Ceva Tiergesundheit (Riems) GmbH
An der Wiek 7
17493 Greifwald-Insel Riems
Germany

17. Other information

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.