LABELLING AND PACKAGE LEAFLET

LABELLING

PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGE UNITS
Lyophilizate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TRICHOVEC Lyophilisate and solvent for suspension for injection for cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Per ml reconstituted vaccine::

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

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 ml
4 ml
8 ml

4. ROUTE(S) OF ADMINISTRATION

Intramuscular

5. WITHDRAWAL PERIOD(S)

Meat: 14 days

6. BATCH NUMBER

Batch

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING (LABEL) OF THE DILUENT

1. NAME OF THE DILUENT

DILUENT A

2. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

10 ml
40 ml
80 ml

3. ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

4. STORAGE CONDITIONS

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

5. BATCH NUMBER

Batch

6. EXPIRY DATE

EXP {month/year}

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

Company logo or name of company

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TRICHOVEC Lyophilisate and solvent for suspension for injection for cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml of reconstituted vaccine contains:

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

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection for cattle.

4. PACKAGE SIZE

5 x 10 m
1 x 40 ml
1 x 80 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Both prevention and therapeutic treatment of trichophytosis in cattle from one day of age

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Meat: 14 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 51609/5000

17. MANUFACTURER'S BATCH NUMBER

Batch

PACKAGE LEAFLET

PACKAGE LEAFLET:

TRICHOVEC, Lyophilisate and solvent for suspension for injection for cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Animal Health Distributors Limited
Tullow Industrial Estate
Bunclody Road
Tullow
Carlow
R93WOD8
Ireland

Manufacturer responsible for batch release:
Bioveta, a.s.
Komenského 212/12
Ivanovice na Hané
683 23 Czech Republic.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Brownish grey lyophilisate and solvent for suspension for injection

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

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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)

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cattle

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.
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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

Meat: 14 days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2°C - 8°C).
Protect from frost.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.
Shelf life after reconstitution according to directions: use immediately

12. SPECIAL WARNING(S)

Special warnings for each 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 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.

Pregnancy and lactation:
Can be used during pregnancy

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 effectiveness of this vaccine when used with any other product. A decision to use this vaccine before or after any other product needs to be made on a case by case basis.

Overdose (symptoms, emergency procedures, antidotes):
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.

Incompatibilities:
This vaccine must not be mixed with any other product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

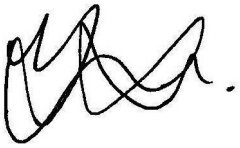
{DD/MM/YYYY}

15. OTHER INFORMATION

The product is supplied in packages of 5 x 10 ml, 1 x 40 ml and 1 x 80 ml.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorization holder.



Approved: 13 June 2023