

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box - package size 5 x 10 ml (*resp. 1 x 40 ml, 1 x 80 ml*)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TRICHOBEN AV

Lyophilisate and solvent for suspension for injection for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition in 1 ml:

A) Lyophilisate

Active substance:

Trichophyton verrucosum avirulentum strain TV-M-310 min. 3.125×10^6 CFU, max. 18.75×10^6 CFU

Excipients:

0.8% sodium chloride solution

Lyophilisation medium

B) Diluent

Diluent A 1 ml

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

5 x 10 ml (*resp. 1 x 40 ml, 1 x 80 ml*)

5. TARGET SPECIES

Cattle from the age of one day.

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTE OF ADMINISTRATION

Intramuscular to the lumbar or gluteal region. Vaccination and revaccination must be performed always to the opposite half of the body. We recommended performance of vaccination into the left half of the body; revaccination should be made into the right half of the body.

8. WITHDRAWAL PERIOD

Withdrawal period: Meat - 14 days.

9. SPECIAL WARNING

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

The vaccine must be used within 2 hours after reconstitution.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated. Do not freeze.

Protect from light.

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

Used vials and devices need to be inactivated; they cannot be left in the stable. It is appropriate to use 2 % Ajatin solution, 1 % peracetic acid solution (for a period of 4 hours) for inactivation or it is possible to perform heat inactivation (100°C, 2 hours).

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

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

Bioveta, a.s., Komenského 212, 683 23 Ivanovice na Hané, Czech Republic

16. MARKETING AUTHORISATION NUMBER

To be completed nationally

17. MANUFACTURER’S BATCH NUMBER

Batch

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate - label
Package size 10 ml (*resp. 40 ml, 80 ml*)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TRICHOBEN AV

Lyophilisate and solvent for suspension for injection for cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE

1 ml:

Trichophyton verrucosum avirulentum strain TV-M-310 min. 3.125×10^6 CFU, max. 18.75×10^6 CFU

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

10 ml (*resp. 40 ml, 80 ml*)

4. ROUTE OF ADMINISTRATION

Intramuscular.

5. WITHDRAWAL PERIOD

Withdrawal period: Meat - 14 days.

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP:

The vaccine must be used within 2 hours after reconstitution.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Diluent A (solvent) - label
Package size 10 ml (*resp. 40 ml, 80 ml*)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diluent A - solvent for TRICHOBEN AV

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Composition - 1 ml:

Natrii chloridum – 8.34 mg
Kalii chloridum – 0.21 mg
Dinatrii phosphas dodecahydricus – 2.47 mg
Kalii dihydrogenphosphas – 0.21 mg
Aqua pro iniectione - ad 1 ml

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

10 ml (*resp. 40 ml, 80 ml*)

4. ROUTE OF ADMINISTRATION

Read the package insert of the vaccine before use.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

