

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton containing 1 x 5 calf doses

Outer carton containing 1 x 20 calf doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Ringvac

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

After reconstitution 1 ml contains $\geq 7 \times 10^6$ and $\leq 21 \times 10^6$ viable microconidia of *Trichophyton verrucosum* strain LTF-130.

3. PHARMACEUTICAL FORM

Lyophilisate and Solvent for Suspension for Injection for Cattle

4. PACKAGE SIZE

1 x 5 calf doses

1 x 20 calf doses

5. TARGET SPECIES

Cattle.

6. INDICATION(S)

For active immunisation of cattle to reduce clinical signs of ringworm and to shorten the recovery time of infected cattle showing clinical signs of ringworm.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Reconstitute the freeze-dried vaccine in the solvent provided.

Shake well before use.

Dosage and administration:

Calves from 2 weeks to 4 months of age: 2 ml.

Older cattle: 4 ml.

Administration is by intramuscular injection preferably in the neck.

Can be used during pregnancy.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Expiry end of:

Once reconstituted, the contents of the vaccine vial should be used within 4 hours.

11. SPECIAL STORAGE CONDITIONS

Store at +2°C to +8°C.

Do not freeze.

Protect from light.

Keep the container in the outer carton.

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

Read the package leaflet before use.

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

[Distribution category]

For animal treatment only.

POM-V

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

MA Holder:

MSD Animal Health UK Ltd.

Walton Manor, Walton

Milton Keynes

MK7 7AJ

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4619

17. MANUFACTURER'S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING

UNITS

Vial containing 1 x 5 calf doses
Vial containing 1 x 20 calf doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Ringvac

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Trichophyton verrucosum min 7×10^6 and max 21×10^6 viable microconidia strain LTF-130 per ml of reconstituted product.

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

One vial contains 5 calf doses.

One vial contains 20 calf doses.

4. ROUTE(S) OF ADMINISTRATION

Dose: Calves 2 ml, calves over 4 months of age: 4 ml by i.m. injection.

Reconstitute the contents of 1 vial in 10 ml of solvent.

Reconstitute the contents of 1 vial in 40 ml of solvent.

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

Expiry end of:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Store at +2°C to +8°C. Do not freeze.

Protect from light.

Keep the container in the outer carton.

Read package leaflet before use.

To be supplied only on veterinary prescription.

POM-V

MA Holder:

MSD Animal Health UK Ltd.

Walton Manor, Walton

Milton Keynes

MK7 7AJ

Vm 01708/4619

PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT LABEL

10 ml Bottle Label

40 ml Bottle Label

1. NAME OF THE DILUENT

Solvent for Bovilis Ringvac

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

10 ml sterile solvent for reconstituting live attenuated *Trichophyton verrucosum* vaccine.

40 ml sterile solvent for reconstituting live attenuated *Trichophyton verrucosum* vaccine.

3. ROUTES OF ADMINISTRATION

Read package leaflet before use.

4. STORAGE CONDITIONS

Store at +2°C to +8°C. Do not freeze.

5. BATCH NUMBER

Batch:

6. EXPIRY DATE

Expiry end of:

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

Vm 01708/4619

PACKAGE LEAFLET FOR:

Bovilis Ringvac

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

Marketing authorisation holder:

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release¹:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

MSD Animal Health UK Limited Walton
Manor, Walton, Milton Keynes
Buckinghamshire, MK7 7AJ
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Ringvac
Lyophilisate and solvent for suspension for injection.

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

Active substance(s)	Per ml of reconstituted product:
<i>Trichophyton verrucosum</i>	$\geq 7 \times 10^6$ and $\leq 21 \times 10^6$ viable microconidia strain LTF-130

4. INDICATION(S)

For active immunisation of cattle to reduce clinical signs of ringworm caused by *Trichophyton verrucosum* (prophylactic dose) and to shorten the recovery time of infected cattle showing clinical signs of ringworm (therapeutic dose).

¹ The printed package leaflet will state the name and address of the manufacturer responsible for the release of the concerned batch only.

Onset of immunity has been demonstrated at 3 weeks after completion of the recommended course.

The duration of protection has not been determined but experience of use in the field suggests that after the recommended course has been completed cattle continue to be protected without re-vaccination.

5. CONTRAINDICATIONS

Do not vaccinate cattle already infected with or in the incubation of an infection with *Trichophyton verrucosum* with the prophylactic dose. In such cases, animals show signs of the disease which could be severe.

6. ADVERSE REACTIONS

Three to eight days after vaccination a local reaction characterised by local swellings, hairless places or crust forming (up to 2 cm diameter) which however decreases after 3 weeks, may occur at the injection site.

Only local reactions and slight temperature rise were observed after vaccination with 10 times the normal dose.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle.

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

Dosage:

Prophylaxis:

Calves from 2 weeks to 4 months: 2 ml

Older cattle:

4 ml

Therapy:

Calves from 2 weeks to 4 months: 4 ml

Older cattle:

8 ml

Administration

Administration is by intramuscular injection preferably in the neck.

Initially the whole herd should be vaccinated with a course of 2 vaccinations, 10-14 days apart. Subsequently, for closed herds only young calves require revaccination at around 2 weeks of age, followed by a second injection 10-14 days later. New

animals introduced into the herd should receive a full vaccination course at the appropriate dosage. No subsequent doses are required.
Can be used during pregnancy.

9. ADVICE ON CORRECT ADMINISTRATION

Do not use chemicals, e.g. alcohol, for sterilisation. Use fresh sterilised equipment for each injection.

The required dose is prepared by reconstituting the vaccine with the accompanying solvent.

Reconstitution of the 20-dose presentation: Reconstitute the vaccine immediately before use by transferring about 5 ml of solvent to the vaccine vial using a sterile needle and syringe. Agitate the vial to ensure that the lyophilisate is fully dissolved and syringe the entire contents into the solvent vial to mix with the remaining diluent.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2°C to 8°C).

Do not freeze.

Protect from light.

Do not use after the expiry date stated on the label and carton.

Keep the container in the outer carton.

Shelf-life after reconstitution according to directions: Reconstituted vaccine should be used within the shortest time period necessary without exceeding a 4 hour period.

12. SPECIAL WARNING(S)

Special precautions for use in animals

Occasional hypersensitivity reactions may occur. In such cases appropriate treatment with e.g. adrenaline should be given without delay.

Operator warnings

Immuno-suppressed individuals should not use the product.

In case of accidental self-injection, seek medical advice and show the package leaflet or label to the physician.

Interactions

No information is available on the safety and efficacy of this vaccine with any other veterinary medicinal product. A decision to use this vaccine before or after any other

veterinary medicinal product is therefore on a case by case basis.
Do not mix with any other veterinary medicinal products except the solvent supplied for use with the vaccine.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2022

15. OTHER INFORMATION

For animal treatment only.

ATCvet code : QI02AP01 – *Live fungal vaccine*

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

Pack sizes

Cardboard box with 1 x 5 calf doses and 1 x 10 ml solvent in glass bottles closed with a rubber stopper/aluminium combination cap.

Cardboard box with 1 x 20 calf doses and 1 x 40 ml solvent in glass bottles closed with a rubber stopper/aluminium combination cap.

For both presentations the vaccine is contained in 10 ml glass vials of Ph.Eur. Type I quality, while the solvent is contained in 10 ml (5-dose presentation) or 50 ml (20- dose presentation) glass vials of Ph.Eur. Type II quality. Both the vaccine and the solvent vials are closed with bromobutyl rubber stoppers of Ph.Eur. Type I quality.

Not all pack sizes may be marketed.

MA number:

Vm 01708/4619

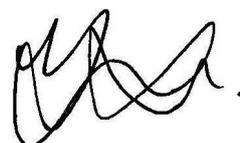
POM-V

Legal category:

To be supplied only on veterinary prescription.

Distributor in Northern Ireland:

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24



Approved: 31 May 2022