PACKAGE LEAFLET

Bovilis Ringvac 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:
Intervet International B.V.
Wim de Körverstraat 35
NL-5831 AN Boxmeer
represented by the national companies in the concerned Member States

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
NL-5831 AN Boxmeer

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Ringvac lyophilisate and solvent for suspension for injection for cattle

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

1 ml of reconstituted vaccine contains:
Attenuated *Trichophyton verrucosum,* strain LTF-130 $\geq 9 \times 10^6$ and $\leq 21 \times 10^6$ viable microconidia.

Lyophilisate: off white to light brown coloured pellet.
Solvent: clear colourless solution.
Reconstituted product: off white to grey homogenous suspension.

4. INDICATIONS

Active immunisation of calves and cattle at risk of infection, or calves and cattle suffering from dermatophytosis induced by *Trichophyton verrucosum*. The prophylactic vaccination reduces clinical signs of *Trichophyton verrucosum* induced dermatophytosis while the therapeutic use results in a 2-fold faster recovery of animals which already show clinical signs of disease.

Onset of immunity: 3 weeks after vaccination.
Duration of immunity: at least one year as demonstrated in a laboratory study.

5. CONTRAINDICATIONS

Do not use in animals with fever and / or with dermatophytosis -independent symptoms of an infectious disease.
Do not use in animals that are treated with corticosteroids.

6. ADVERSE REACTIONS

After vaccination very commonly a local reaction characterised by swelling may be observed for 3 to 8 days. Hairless places or very small crusts – up to 2 centimeter diameter – may occur at the injection site very commonly. These decrease slowly after 3 weeks over a period up to 3 months.
Mainly after therapeutic use an increase of the body temperature up to 2.5 °C may very rarely be observed for up to two days.
Animals which are in the incubation phase at the time of vaccination may develop the disease in spite of vaccination. However, the skin changes heal within approx. four weeks after the second injection.

In very rare cases a hypersensitivity reaction e.g. anaphylactic reaction may occur after vaccination.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

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

Administration:
Intramuscular injection, preferably in the side of the neck, with an interval of 10 - 14 days.

Dosage:	Prophylactic vaccination		Therapeutic use	
	Calves up to four months:	2 ml	Calves up to four months:	5 ml
	Animals over 4 months:	4 ml	Animals over 4 months:	10 ml

Basic vaccination
The entire herd should be vaccinated twice with an interval of 10 - 14 days.

Further vaccinations
After the whole herd is vaccinated, only newly born calves or additionally purchased animals are vaccinated twice with an interval of 10 - 14 days. No revaccination is necessary if all the animals of the herd are vaccinated.

Preparation of the vaccine:
Before application, resuspend the lyophilisate with the solvent. Shake well to achieve complete suspension.

9. ADVICE ON CORRECT ADMINISTRATION

Successive injections should be administered at alternative sides of the body.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Lyophilisate: Store in a refrigerator (2 °C – 8 °C).
Protect from light.
Solvent: Store below 25 °C if stored independently from the vaccine.
Reconstituted product: Keep below 25 °C.

Shelf-life after reconstitution according to directions: 6 hours.

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

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Trichophyton verrucosum can survive in the environment for 6-8 years. It is recommended to combine a vaccination program with a cleaning and disinfection protocol.
Preparations with antifungal activity should not be given while immunization is ongoing until three weeks after completion of vaccination.
Vaccinated animals should not be housed among non-vaccinated animals showing clinical signs of *Trichophyton verrucosum* infection before having reached full immunity. Animals introduced into a vaccinated herd should either be free of dermaphytosis or be vaccinated therapeutically and kept separate until they are fully recovered from disease.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection seek medical advice immediately and show the package insert or label to the physician.

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.

Overdose (symptoms, emergency procedures, antidotes):
No adverse reactions other than those mentioned in section 6 were observed after the administration of a ten-fold overdose.

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with the local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes:
Cardboard box with 1 vial lyophilisate and 1 x 10 ml solvent.
Cardboard box with 1 vial lyophilisate and 1 x 40 ml solvent.

Not all pack sizes may be marketed.

Veterinary medicinal product subject to prescription.