SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Ringvac

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use specifying the target species

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).
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.

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals.

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.
Use fresh sterilised equipment for each injection.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Immuno-suppressed individuals should not use the product.
In case of accidental self-injection, seek medical advice and show the package insert or label to the physician.

4.6 Adverse reactions (frequency and seriousness)

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, decrease after 3 weeks, may occur at the injection site.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

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.

4.9 Amounts to be administered and administration route

Dosage:

Prophylaxis:		Therapy:	
Calves from 2 weeks to 4 months:	2 ml	Calves from 2 weeks to 4 months:	4 ml
Older cattle:	4 ml	Older cattle:	8 ml

Administration
Administration is by intramuscular injection preferably in the neck.
Do not use chemicals, e.g. alcohol, for sterilisation.

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 diluent 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 diluent vial to mix with the remaining diluent.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes)(if necessary)

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

4.11 Withdrawal periods

Zero days.

5. IMMNOLOGICAL PROPERTIES

ATC code: QI02AP01 – Live fungal vaccine
To stimulate active immunity against ringworm in cattle cause by *Trichophyton verrucosum*.

6. PHARMACETUICAL PARTICULARS

6.1 List of excipients

Vaccine:
Gelatin
Sucrose
Solvent:
Sodium chloride
di-sodium hydrogen phosphate $2H_2O$
Potassium di-hydrogen phosphate
Water for injections

6.2 Incompatibilities

Do not mix with any other veterinary medicinal products except the solvent supplied for use with the vaccine.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
Vaccine: 2 years
Solvent: 3 years
Shelf life after dilution or reconstitution according to directions
Reconstituted vaccine should be used within the shortest time period necessary without exceeding a 4 hour period.

6.4 Special precautions for storage

Store in a refrigerator (2°C to 8°C). Do not freeze. Protect from light

6.5 Nature and composition of immediate packaging

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 into 10 ml glass vials of Ph.Eur. Type I quality, while the solvent is contained into 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 presentation may be marketed.

6.6 Special precautions for disposal of unused veterinary medicinal product or waste material derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4113

9. DATE OF FIRST AUTHORISATION

23 September 2005

10. DATE OF REVISION OF THE TEXT

November 2024

Approved 18 November 2024
Gavin Hall