Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Ringvac lyophilisate and solvent for suspension for injection for cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per 1 ml of vaccine:

Active substance:
Attenuated *Trichophyton verrucosum*, strain LTF - 130 ≥9 x 10^6 and ≤21 x 10^6 viable microconidia.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

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

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

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.

4.3 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.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals
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.

4.6 Adverse reactions (frequency and seriousness)

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)

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

Administration:
Intramuscular injection, preferably in the side of the neck, with an interval of 10 - 14 days. Successive injections should be administered at alternative sides of the body.

*Dosage:*Prophylactic vaccinationTherapeutic use
Calves up to four months: 2 ml Calves up to four months: 5 ml
Animals over four months: 4 ml Animals over four 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.

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

No adverse reactions other than those mentioned in section 4.6 were observed after the administration of a ten-fold overdose.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunological for cattle, live fungal vaccine, trychophyton.
ATC vet code: QI02AP01.

To stimulate active immunity against dermatophytosis caused by *Trichophyton verrucosum*.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate
Gelatin
Sucrose
Purified water

Solvent
Sodium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf-life

Shelf life of the lyophilisate: 2 years
Shelf life of the solvent: 3 years
Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after reconstitution according to directions: 6 hours

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Lyophilisate: Glass vial closed with a halogenobutyl rubber stopper and an aluminium cap.
Solvent: Glass vial of 10 ml or 40 ml closed with a halogenobutyl rubber stopper and an aluminium cap.

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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
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Magna Business Park, Citywest Road
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8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/284/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 April 2017

10 DATE OF REVISION OF THE TEXT

August 2021