

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis IBR

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

<i>Active Substance(s):</i>	per dose (2 ml)
IBR virus, strain INT 1	$\geq 5.6 \log_{10} \text{TCID}_{50}$
grown in BEL 26 cells.	

Other ingredient(s):
Traces of neomycin, polymixin, or gentamycin and amphotericin may be present in the product.

Diluent:
No ingredients knowledge of which is essential for the safe use of the product.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

For the active immunisation of cattle to reduce both clinical signs of disease and virus excretion after infection with infectious bovine rhinotracheitis. The degree of protection afforded by use of the intramuscular route is slightly less than following intranasal administration.

Cattle have been shown to be protected from the worst clinical effects of IBR within 2 days of intranasal and 7 days of intramuscular vaccination with Bovilis IBR.

Where an outbreak of IBR occurs, in-contact animals may be vaccinated immediately with Bovilis IBR in an attempt to prevent or reduce the severity of the disease. The vaccine should be used intranasally for this purpose.

Annual revaccination is recommended.

4.3 Contraindications

None known

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

Only healthy animals should be vaccinated.

Special precautions to be taken by the person administering the medicinal product to animals

In the event of self-injection with this vaccine resulting in signs of local or systemic reaction, seek medical advice.

4.6 Adverse reactions (frequency and seriousness)

No adverse effects have been observed.

4.7 Use during pregnancy, lactation or lay

Bovilis IBR has been shown to have no adverse effects when administered to pregnant animals by either the intra-nasal or intramuscular route.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with this product.

4.9 Amounts to be administered and administration route

The vaccine should be reconstituted immediately before use with the diluent supplied thus:

5 dose of vaccine:

All 10 ml of the diluent is syringed into the vaccine vial and this is agitated until the plug is fully dissolved.

25 dose vial of vaccine:

About 10 ml of the 50 ml vial of diluent is syringed into the vaccine vial and this is agitated until the plug is fully dissolved. The entire contents of the vaccine vial are then syringed into the diluent vial and mixed with the remaining diluent.

The preferred route of administration is by intra-nasal application, from 6 weeks of age. If intranasal administration is not possible, e.g., cattle not used to being handled, the vaccine may be given as an intramuscular injection in cattle of 12 weeks of age or more.

Intranasal administration:

Reconstituted vaccine should be drawn into a suitable syringe and the applicator provided should be attached. The dose per animal is 2 ml of reconstituted vaccine administered intranasally, instilling 1 ml of vaccine into each nostril. The applicator can be inserted by guiding it medially and ventrally along the nasal septum. Care should be taken to avoid spillage by holding up the head of the animal during administration and by ensuring that the applicator is inserted fully into the nostril.

Intramuscular injection:

A single injection of 2 ml reconstituted vaccine, observing the normal aseptic precautions. Use clean equipment for administration but avoid contamination of vaccine with traces of disinfectant or spirit.

Vaccination programme:

Calves can be vaccinated at any age over 6 weeks by the intranasal route, but animals vaccinated below the age of 12 weeks should receive a further vaccination at or after reaching this age, since MDA may interfere with vaccine 'take' below this age.

Animals over 12 weeks of age should be given a single dose of vaccine.

Further information:

Bovilis IBR has been given to calves 4 weeks of age by the intranasal route without adverse effects, but efficacy has not been investigated in calves less than 6 weeks of age.

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

Adverse reactions, with the exception of the possibility of a transient (1-2 days), slight (<1°C) pyrexia, are not expected.

4.11 Withdrawal Period(s)

Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC QI02AD01

Vaccine contains attenuated IBR virus for the induction of active immunity in the target species, cattle.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol
Gelatin
Pancreatic digest of casein
Disodium phosphate dihydrate
Water for injections
Traces of antibiotics, cell culture medium may be present

6.2 Incompatibilities

Vaccine should not be reconstituted except with the diluent provided (Unisolve), and should not be mixed with other products.

6.3 Shelf-life

Vaccine:
24 months

Diluent:
60 months
Reconstituted vaccine should be used immediately and should not be stored.

6.4 Special precautions for storage

Vaccine:
Store between at +2°C - 8°C. Do not freeze. Protect from light. Care should be taken to avoid prolonged or repetitive exposure to high ambient temperatures following withdrawal from the refrigerator prior to use.

Diluent:
Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Vaccine:
Clear, Glass Hydrolytic Type I vial with halogenobutyl rubber stopper, closed with a colour coded aluminium cap.
Vials containing 5 or 25 doses.

Diluent:
Clear, Glass Hydrolytic Type II vial with halogenobutyl rubber stopper, closed with a colour coded aluminium crimp cap. Vials containing 10 or 50 ml.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.,
Cookstown Industrial Estate,
Tallaght,
Dublin 24.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/78/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

6th June 2003