Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Bovipast RSP suspension for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per 1 dose (5 ml):

Active substances

inact. BRS-Virus, strain EV908	at least	$10^{5.5}$	$TCID_{50}$*
	max	$10^{6.4}$	$TCID^{50}$
inact. Parainfluenza-3-Virus, strain SF-4 Reisinger	at least	$10^{7.3}$	$TCID_{50}$*
	max	$10^{8.3}$	$TCID_{50}$
inact. *Mannheimia haemolytica* A1, strain M4/1		9×10^9	cells

* Antigen concentration that induces antibody levels in rabbits not significantly lower than that of a standard preparation; $TCID_{50}$ = tissue culture infective dose 50%

Adjuvants

Aluminium hydroxide	37.5	mg
Quil A (Saponin)	0.625	mg

Excipients

Thiomersal	0.037	mg

3 PHARMACEUTICAL FORM

Suspension for injection.

The product is pale yellow to red-pink with whitish sediment. By shaking the sediment is easily suspended to an opaque, whitish to red/pink suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

For the active immunisation of cattle against:
-Parainfluenza 3 virus, to reduce infection,
-Bovine Respiratory Syncytial virus, to reduce infection and clinical signs,
-*Mannheimia haemolytica* serotype A1, to reduce infection, mortality, clinical signs, lung lesions and bacterial invasion of the lung caused by serotypes A1 and A6.
Cross-reactive immunity to the A6 serotype of *M.haemolytica* has been demonstrated in a challenge experiment under laboratory conditions after primary course of vaccination.
Approximately two weeks after completion of the basic immunisation programme, the humoral immune response against BRS-Virus and PI-3-Virus is at its highest level. The duration of protective immunity has not been established in challenge experiments.

4.3 Contraindications

Do not vaccinate animals that have intercurrent disease, heavy parasitic infestation or are in poor general condition, since a satisfactory immune response will only be obtained in healthy and immuno-competent animals.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals:
The basic immunisation should be started in time, so that immunity has fully developed by the beginning of the period of risk. The basic immunisation of calves should be completed prior to housing or should be performed in the housing unit under quarantine.

It is advisable to vaccinate all animals in a herd in order to minimise the infectious potential unless there is a contraindication. Failure to vaccinate individual animals may promote the transmission of pathogens and development of disease.

The magnitude of the antibody response may be reduced by maternally derived antibodies in calves up to six weeks of age. However, according to the results of challenge experiments, significant protection against infection by BRS-Virus is still provided three weeks after the basic vaccination course, and significant protection against PI-3-Virus and *Mannheimia haemolytica* serotype A1 is still provided six weeks after the basic vaccination course. The results of challenge experiments in calves with maternally derived antibodies further indicate that the onset of cross-protective immunity to the A6 serotype is 2 weeks after completion of the vaccination course. Cross protective immunity is provided up to six weeks after the basic vaccination course as demonstrated by serological tests.

Respiratory infections in calves are often associated with poor hygiene. Thus, general improvements in hygiene are important to support the effect of vaccination.

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

4.6 Adverse reactions (frequency and seriousness)

Immunisation may commonly result in temporary swellings at the injection site (in extreme cases narrow swellings up to 10cm long may occur). Typically, these swellings completely disappear or reduce in size to a negligible small lump within 2 to 3 weeks after vaccination, though in individual animals very small reactions can be found for up to 3 months. Additionally, a transient slight rise in body temperature, lasting a maximum of 3 days, may commonly occur after vaccination and at the same time a slight reluctance to move may be found.

In very rare cases hypersensitivity reactions may occur.

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 interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with MSD Animal Health's live IBR marker vaccine (where this product is authorised) in cattle from 3 weeks of age onwards.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. 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.
Immunosuppressive drugs should generally not be used directly before or after vaccination, since a satisfactory immune response will only be obtained in immuno-competent animals.

4.9 Amounts to be administered and administration route

Dose:
5 ml

Method of administration:
Subcutaneous injection into the side of the neck.

Basic immunisation:
Animals from approximately 2 weeks of age should receive two vaccinations separated by an interval of approximately 4 weeks.

Booster doses:
If booster doses are required, a single dose should be given approximately 2 week before each risk period (e.g. transport, introduction into a herd, change of housing).

The vaccine must be shaken well before use.
For vaccine administration, needles of 1.5 to 2.0 mm diameter and 10 to 18 mm long are recommended. The vaccine should be brought to room temperature prior to use and injected quickly.

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

Accidental overdosage is unlikely to cause any reaction other than described in section 4.6, however the swelling may be larger and temperature rise may be higher.

4.11 Withdrawal Period(s)

Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

The vaccine contains as active ingredients inactivated BRS-Virus (strain EV 908) and Parainfluenza-3-Virus (strain SF-4 Reisinger) as well as inactivated *Mannheimia haemolytica* bacteria (serotype A1) propagated under conditions of iron restriction. Aluminium hydroxide and Quil A are included as adjuvants. Thiomersal serves as preservative.

The vaccine induces antibodies against BRS-Virus, PI-3-Virus and *Mannheimia haemolytica*.
ATC vet code: QI02AL04

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal

6.2 Incompatibilities

None known. Do not mix with any other veterinary medicinal product .

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 28 months
Shelf-life after first opening the immediate packaging: 10 hours

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C). Protect from light and frost.

6.5 Nature and composition of immediate packaging

50 ml bottles of type I glass, Ph. Eur., closed with injection stoppers type I rubber, Ph. Eur., sealed with an aluminium crimp cap.

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

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

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/152/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th June 2000

Date of last renewal: 9th October 2009

10 DATE OF REVISION OF THE TEXT

October 2015