

## **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Bovipast RSP suspension for injection for cattle

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (5 ml) contains:

### Active substances:

Inactivated Bovine Respiratory Syncytial virus, strain EV908	$10^{4.77} - 10^{5.45}$	U/dose*
Inactivated Parainfluenza-3Virus, strain SF-4 Reisinger	$10^{3.54} - 10^{4.85}$	U/dose*
Inactivated <i>Mannheimia haemolytica</i> A1, strain M4/1	$10^{4.24} - 10^{5.00}$	U/dose*

\* Results obtained with AlphaLISA assays

### Adjuvants:

Aluminium hydroxide	37.5 mg
Quil A (Saponin)	0.189 – 0.791 mg

### Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Thiomersal	0.032 – 0.058 mg
Simethicone	
Formaldehyde	

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

## 3. CLINICAL INFORMATION

### 3.1 Target species

Cattle.

### 3.2 Indications for use for each 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 *Mannheimia 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 Bovine Respiratory Syncytial virus and Parainfluenza-3 virus is at its highest level. The duration of protective immunity has not been established in challenge experiments.

Onset of immunity: 2 weeks.

Duration of immunity: has not been established.

### 3.3 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.

### 3.4 Special warnings

Vaccinate healthy animals only.

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 Bovine Respiratory Syncytial virus is still provided three weeks after the basic vaccination course, and significant protection against Parainfluenza-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.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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 leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Cattle:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling <sup>1</sup> . Elevated temperature <sup>2</sup> , reluctant to move.
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction <sup>3</sup> .

<sup>1</sup> In extreme cases narrow swellings up to 10 cm long. 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.

<sup>2</sup> Slight and lasting a maximum of 3 days after vaccination.

<sup>3</sup> May be fatal.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

{< > to be adjusted nationally}

### **3.7 Use during pregnancy, lactation or lay**

Pregnancy and lactation:

Can be used during pregnancy and lactation.

### **3.8 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 Bovilis IBR Marker Live (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.

### **3.9 Administration routes and dosage**

Method of administration:

Subcutaneous use. Injection into the side of the neck.

Dose:

5 ml.

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 weeks 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.

### **3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)**

Accidental overdosage is unlikely to cause any reaction other than described in section 3.6, however the swelling may be larger and temperature rise may be higher.

**3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance**

**3.12 Withdrawal periods**

Zero days.

**4. IMMUNOLOGICAL INFORMATION**

**4.1 ATCvet code: QI02AL04.**

The vaccine contains as active ingredients inactivated Bovine Respiratory Syncytial 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 Bovine Respiratory Syncytial virus, Parainfluenza-3 virus and *Mannheimia haemolytica*.

**5. PHARMACEUTICAL PARTICULARS**

**5.1 Major incompatibilities**

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

**5.2 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.

**5.3 Special precautions for storage**

Store in a refrigerator (2 °C – 8 °C).

Protect from frost.

Protect from light.

**5.4 Nature and composition of immediate packaging**

Cardboard box with 50 ml bottles of type I glass (10 doses), closed with injection stoppers type I rubber sealed with an aluminium crimp cap.

Pack size:

Cardboard box with 1 glass bottle of 50 ml (10 doses).

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

Medicines should not be disposed of via wastewater <or household waste>.

{<> to be adjusted nationally}

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

**6. NAME OF THE MARKETING AUTHORISATION HOLDER**

{Name}

{< > to be completed nationally}

**7. MARKETING AUTHORISATION NUMBER(S)**

**8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: {DD/MM/YYYY}.

{< > to be completed nationally}

**9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

{MM/YYYY}

{to be completed nationally}

**10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

[BE, DK, EL, ES, FI, IT, LU, NO, PL, PT, SE, UK(NI)]: Veterinary medicinal product subject to prescription.

[IE]: Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

## **LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**



**PARTICULARS TO APPEAR ON THE OUTER PACKAGE****CARDBOARD BOX****1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Bovilis Bovipast RSP suspension for injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each dose (5 ml) contains:

Inactivated Bovine Respiratory Syncytial virus, strain EV908	$10^{4.77} - 10^{5.45}$ U/dose
Inactivated Parainfluenza-3 virus, strain SF-4 Reisinger	$10^{3.54} - 10^{4.85}$ U/dose
Inactivated <i>Mannheimia haemolytica</i> serotype A1, strain M4/1	$10^{4.24} - 10^{5.00}$ U/dose

**3. PACKAGE SIZE**

50 ml (10 doses).

**4. TARGET SPECIES**

Cattle

**5. INDICATIONS****6. ROUTES OF ADMINISTRATION**

Subcutaneous use.

**7. WITHDRAWAL PERIODS**

Withdrawal period: zero days.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use within 10 hours.

**9. SPECIAL STORAGE PRECAUTIONS**

Store in a refrigerator. Protect from frost. Protect from light.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

<b>11. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b>
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For animal treatment only.

<b>12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”</b>
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Keep out of the sight and reach of children.

<b>13. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
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{ Name or company name or logo name of the marketing authorisation holder}  
{to be completed nationally}

<b>14. MARKETING AUTHORISATION NUMBERS</b>
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{ number}  
{to be completed nationally}

<b>15. BATCH NUMBER</b>
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Lot {number}

<b>MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS</b>
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Glass bottle 50 ml
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<b>1. NAME OF THE VETERINARY MEDICINAL PRODUCT</b>
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Bovilis Bovipast RSP



<b>2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES</b>
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Per 5 ml:

Inact.: BRSV, PI-3, *M. haemolytica* A1

50 ml

<b>3. BATCH NUMBER</b>
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Lot {number}

<b>4. EXPIRY DATE</b>
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Exp. {mm/yyyy}

Once broached use within 10 hours.

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Bovilis Bovipast RSP suspension for injection for cattle

### 2. Composition

Each dose (5 ml) contains:

#### Active substances:

Inactivated Bovine Respiratory Syncytial virus, strain EV908	$10^{4.77} - 10^{5.45}$ U/dose*
Inactivated Parainfluenza-3 Virus, strain SF-4 Reisinger	$10^{3.54} - 10^{4.85}$ U/dose*
Inactivated <i>Mannheimia haemolytica</i> A1, strain M4/1	$10^{4.24} - 10^{5.00}$ U/dose*

\* Results obtained with AlphaLISA assays

#### Adjuvants:

Aluminium hydroxide	37.5 mg
Quil A (Saponin)	0.189 – 0.791 mg

#### Excipients:

Thiomersal	0.032 – 0.058 mg
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Pale yellow to red-pink with whitish sediment. By shaking the sediment is easily suspended to an opaque, whitish to red/pink suspension.

### 3. Target species

Cattle.

### 4. Indications for use

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 *Mannheimia 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 Bovine Respiratory Syncytial virus and Parainfluenza-3 virus is at its highest level. The duration of protective immunity has not been established in challenge experiments.

Onset of immunity: 2 weeks.

Duration of immunity: has not been established.

### 5. 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.

## **6. Special warnings**

### Special warnings:

Vaccinate healthy animals only.

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 Bovine Respiratory Syncytial virus is still provided three weeks after the basic vaccination course, and significant protection against Parainfluenza-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 case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

### Pregnancy and lactation:

Can be used during pregnancy and lactation.

### 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 Bovilis IBR Marker Live (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.

### Overdose:

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

### Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

## **7. Adverse events**

Cattle:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling <sup>1</sup> . Elevated temperature <sup>2</sup> , reluctant to move.
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction <sup>3</sup> .

<sup>1</sup> In extreme cases narrow swellings up to 10 cm long. 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.

<sup>2</sup> Slight and lasting a maximum of 3 days after vaccination.

<sup>3</sup> May be fatal.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.  
{< > to be adjusted nationally}

## **8. Dosage for each species, routes and method of administration**

Dose: 5 ml.

Method of administration: Subcutaneous use. 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 weeks before each risk period (e.g. transport, introduction into a herd, change of housing).

## **9. Advice on correct administration**

Shake 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.

## **10. Withdrawal periods**

Zero days.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).

Protect from frost.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 10 hours.

## **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater <or household waste>.

{< > to be adjusted nationally}

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

## **13. Classification of veterinary medicinal products**

BE, DK, EL, ES, FI, IT, LU, NO, PL, PT, SE, UK(NI): Veterinary medicinal product subject to prescription.

IE: Veterinary medicinal product not subject to prescription.

## **14. Marketing authorisation numbers and pack sizes**

Pack size:

Cardboard box with 1 glass bottle of 50 ml (10 doses).

{< > to be adjusted nationally}

## **15. Date on which the package leaflet was last revised**

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

## **16. Contact details**

Marketing authorisation holder< and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:

{< > to be adjusted nationally}

<Manufacturer responsible for batch release:> {to be adjusted nationally if included in the above}

Intervet International B.V.



Wim de Körverstraat 35  
5831 AN Boxmeer  
The Netherlands

<Local representative< and contact details to report suspected adverse reactions>:>  
{<> to be adjusted nationally}

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>  
{<> to be adjusted nationally}

## **17. Other information**

The vaccine contains as active ingredients inactivated Bovine Respiratory Syncytial 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. The vaccine induces antibodies against Bovine Respiratory Syncytial virus, Parainfluenza-3 virus and *Mannheimia haemolytica*.

{to be completed nationally}

