# LABELLING AND PACKAGE LEAFLET

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Carton**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Bovipast RSP suspension for injection for cattle

## 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 *Mannheimia haemolytica* serotype A1, strain M4 | $10^{4.24}$ – $10^{5.00}$ U/dose |

## 3. PHARMACEUTICAL FORM

Suspension for injection

## 4. PACKAGE SIZE

50 ml (10 doses)

## 5. TARGET SPECIES

Cattle

## 6. INDICATION(S)

For OTC products
Vaccine against PI-3-virus, BRS-virus and M. haemolytica serotype A1 and A6.
*[CMS IE only]*

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read package leaflet before use.

## 8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days

## 9. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous.

## 10. EXPIRY DATE

EXP {month/year}
Once broached use within 10 hours.

## 11. SPECIAL STORAGE CONDITIONS

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

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read package leaflet before use.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

## 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/3003

## 17. MANUFACTURER'S BATCH NUMBER

Lot

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Glass bottle 50 ml**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Bovipast RSP suspension for injection for cattle

## 2. QUANTITY OF THE ACTIVE SUBSTANCES

Per 5 ml:
Inact.: BRSV, PI-3, *M. haemolytica* A1

## 3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

## 4. ROUTE(S) OF ADMINISTRATION

SC use

## 5. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days

## 6. BATCH NUMBER

Lot

## 7. EXPIRY DATE

EXP
Once broached use within 10 hours.

## 8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

# PACKAGE LEAFLET:
# Bovilis Bovipast RSP suspension for injection for cattle

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
NL-5831 AN Boxmeer

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Bovipast RSP suspension for injection

## 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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 *Mannheimia haemolytica* 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 |

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. INDICATION(S)

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.

## 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. ADVERSE REACTIONS

In laboratory studies and field trials:
Immunisation may commonly result in temporary swellings at the injection site (in extreme cases narrow swellings up to 10 cm 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 post marketing experience:
In very rare cases hypersensitivity reactions, which may be fatal, can occur.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

## 7. TARGET SPECIES

Cattle.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 PERIOD(S)

Zero days.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 ºC – 8 ºC).
Protect from frost.
Protect from light.

Shelf life after first opening the container: 10 hours.

## 12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.

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 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 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.

Overdose (symptoms, emergency procedures, antidotes)
Accidental overdosage is unlikely to cause any reaction other than described in section 6, however the swelling may be larger and temperature rise may be higher.

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

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

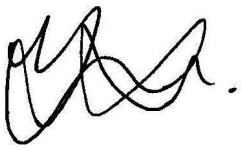
## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2023

## 15. OTHER INFORMATION

Pack size: Carton box with 1 glass bottle of 50 ml (10 doses).

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*.



Approved: 24 March 2023