PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{Cardboard box or label for plastic box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pneumovac Plus suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:

Bovine respiratory syncytial virus (BRSV), strain BIO 24, inactivated	RP ≥ 1*
Bovine parainfluenza 3 virus (PI3V), strain BIO 23, inactivated	RP ≥ 1*
Bovine viral diarrhoea virus, strain BIO 25 (BVDV), inactivated	RP ≥ 1*
Mannheimia haemolytica, Strain DSM 5283, serotype 1A, inactivated	RP ≥ 1*

*RP - Relative Potency

3. PACKAGE SIZE

1 x 10 ml (5 doses),
10 x 10 ml (50 doses),
1 x 50 ml (25 doses),
1 x 100 ml (50 doses)

4. TARGET SPECIES

Cattle

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

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

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Animal Health Distributors Limited
<Logo>

14. MARKETING AUTHORISATION NUMBERS

Vm 51609/4001

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
{Glass vial 100 ml, Plastic vial 100 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pneumovac Plus suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml dose contains:

Bovine respiratory syncytial virus (BRSV), strain BIO 24, inactivated	RP ≥ 1*
Bovine parainfluenza 3 virus (PI3V), strain BIO 23, inactivated	RP ≥ 1*
Bovine viral diarrhoea virus, strain BIO 25 (BVDV), inactivated	RP ≥ 1*
Mannheimia haemolytica, Strain DSM 5283, serotype 1A, inactivated	RP ≥ 1*

*RP - Relative Potency

3. TARGET SPECIES

Cattle.

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
S.C.

5. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Animal Health Distributors Limited
<Logo>

9. BATCH NUMBER

Lot {number}
100 ml (50 doses)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
{Glass vials 10 ml, 50 ml, Plastic vials 10 ml, 50 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pneumovac Plus

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each 2 ml dose contains:

Bovine respiratory syncytial virus (BRSV), strain BIO 24, inactivated	RP ≥ 1*
Bovine parainfluenza 3 virus (PI3V), strain BIO 23, inactivated	RP ≥ 1*
Bovine viral diarrhoea virus, strain BIO 25 (BVDV), inactivated	RP ≥ 1*
Mannheimia haemolytica, Strain DSM 5283, serotype 1A, inactivated	RP ≥ 1*

*RP - Relative Potency

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 10 hours.

10 ml (5 doses) / 50 ml (25 doses)

<Logo>

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:
PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Pneumovac Plus suspension for injection for cattle

2. Composition

Each 2 ml dose contains:

Active substances:

Bovine respiratory syncytial virus (BRSV), strain BIO 24, inactivated	RP ≥ 1*
Bovine parainfluenza 3 virus (PI3V), strain BIO 23, inactivated	RP ≥ 1*
Bovine viral diarrhoea virus, strain BIO 25 (BVDV), inactivated	RP ≥ 1*
Mannheimia haemolytica, Strain DSM 5283, serotype 1A, inactivated	RP ≥ 1*

*RP - Relative Potency (ELISA) in comparison with the reference serum obtained after vaccination of guinea pigs with a vaccine batch that has successfully passed the challenge test in the target animals.

Adjuvants:

Aluminium hydroxide	8.0 mg
Quillaja saponin (Quil A)	0.4 mg

Excipients:

Thiomersal	0.2 mg

Pinkish liquid with sediment.

3. Target species

Cattle.

4. Indications for use

For active immunisation of cattle against:

Bovine parainfluenza 3 virus (PI3V), to reduce the quantity and duration of virus excretion.
Bovine respiratory syncytial virus (BRSV), to reduce the quantity and duration of virus excretion.
Bovine viral diarrhoea virus (BVDV), to reduce the quantity and duration of virus excretion.
Mannheimia haemolytica Serotype 1A, to reduce clinical signs and lung lesions.

Onset of immunity: 3 weeks after primary vaccination course.
Duration of immunity: 6 months after primary vaccination course.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
The efficacy of vaccination has not been demonstrated in the presence of antibodies. The level of antibody response may be reduced by the presence of maternal antibodies. In the presence of maternal antibodies timing of initial vaccination of calves should be planned accordingly.

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:
Do not use during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
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.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1]
Common (1 to 10 animals / 100 animals treated):	Elevated temperature[2]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactic-type reactions[3]

[1] Up to 10 cm or more in diameter and may be associated with pain. Disappears within 6 weeks after vaccination.
[2] Increase in body temperature (1.5 °C at most) lasting up to 3 days after vaccination.
[3] Appropriate symptomatic treatment should be administered.

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 using the contact details at the end of this leaflet, or via your national reporting system at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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

Subcutaneous use (S.C.).
Vaccine dose – 2 ml.

Primary vaccination:
Calves from non-immune dams: 2 injections 3 weeks apart from 2 weeks of age.
For calves from immune dams or where the immune status of the dam is unknown the vaccination scheme should be adapted at the discretion of the veterinarian to take into account potential interference of maternally derived antibodies with the response to vaccination.

Revaccination:
Administer a single dose 6 months after completion of the primary vaccination scheme. The efficacy of revaccination was demonstrated by measurement of the serological response. The efficacy of revaccination has not been assessed by challenge.

9. Advice on correct administration

Warm the vaccine before use to a temperature of 15 °C to 25 °C.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C)
Do not freeze. Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging: 10 hours.

12. Special precautions for disposal

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

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

Veterinary medicinal product subject to prescription.

14. Marketing authorisation number and pack sizes

Marketing authorisation number: Vm 51609/4001

The vaccine is filled in glass vials of hydrolytic type I or II and plastic vials compliant with Ph. Eur. closed with chlorobutyl rubber stoppers and crimped with an aluminium cap.

Pack sizes:
1 x 10 ml, 10 x 10 ml, 1 x 50 ml 1 x 100 ml
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:
Animal Health Distributors Limited
Tullow Industrial Estate
Bunclody Road
Tullow
Carlow
R93 WOD8
Ireland
Phone number: +353 59 9151251

Manufacturer responsible for batch release:
Bioveta, a,.s.,
Komenského 212/12,
683 23 Ivanovice na Hané,
Czech Republic

17. Other information

POM-V

Approved 12 May 2026

Gavin Hall