PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pneumovac Plus suspension for injection for cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose (2ml) contains:

Active substances:

Bovine respiratory syncytial virus inactivated, strain BIO 24	RP ≥ 1*
Bovine parainfluenza 3 virus inactivated, strain BIO 23	RP ≥ 1*
Bovine viral diarrhoea virus, strain BIO 25	RP ≥ 1*
Mannheimia haemolytica inactivated, Strain DSM 5283, serovar 1A	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.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

1 x 10ml, 10 x 10ml, 1 x 50ml, 1 x 100ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For active immunisation of cattle against:

Bovine parainfluenza 3 virus, to reduce the quantity and duration of virus excretion.
Bovine respiratory syncytial virus, to reduce the quantity and duration of virus excretion.

Bovine viral diarrhoea virus, 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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous injection.

Read the package leaflet before use

8. WITHDRAWAL PERIOD

Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

Once opened use within 10 hours

11. SPECIAL STORAGE CONDITIONS

Store and transport in a refrigerator. Do not freeze. Protect from light.

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

Disposal:- read the package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

POM-V			

In Eire the sales category for this product is POM(E)

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

Animal Health Distributors Limited

16. MARKETING AUTHORISATION NUMBER

Vm 51609/4001

17. MANUFACTURER’S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pneumovac Plus suspension for injection for cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose (2ml) contains:

Active substances:

Bovine respiratory syncytial virus inactivated, strain BIO 24	RP ≥ 1*
Bovine parainfluenza 3 virus inactivated, strain BIO 23	RP ≥ 1*
Bovine viral diarrhoea virus, strain BIO 25	RP ≥ 1*
Mannheimia haemolytica inactivated, Strain DSM 5283, serovar 1A	RP ≥ 1*

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

10ml

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous injection

5. WITHDRAWAL PERIOD

Zero days

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP:

Once opened use within 10 hours

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

PACKAGE LEAFLET FOR:

Pneumovac Plus 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:

Animal Health Distributors Limited
Tullow Industrial Estate
Bunclody Road
Tullow
Carlow
R93WOD8
Ireland

Manufacturer responsible for batch release:

Bioveta a.s., Komenskeho 212/12, 683 23 Ivanovice na Hane, Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pneumovac Plus suspension for injection for cattle.

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

Each dose (2ml) contains:

Active substances:

Bovine respiratory syncytial virus inactivated, strain BIO 24	RP ≥ 1*
Bovine parainfluenza 3 virus inactivated, strain BIO 23	RP ≥ 1*
Bovine viral diarrhoea virus, strain BIO 25	RP ≥ 1*
Mannheimia haemolytica inactivated, Strain DSM 5283, serovar 1A	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 mg
Quillaja saponin (Quil A)	0.4 mg

Excipients:

Thiomersal	0.2 mg
Formaldehyde 35% solution	Max 1 mg

Pinkish liquid with sediment

4. INDICATION(S)

For active immunisation of cattle against:

Bovine parainfluenza 3 virus, to reduce the quantity and duration of virus excretion.
Bovine respiratory syncytial virus, to reduce the quantity and duration of virus excretion.
Bovine viral diarrhoea virus, to reduce 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. ADVERSE REACTIONS

A localised swelling may be very commonly observed at the injection site after vaccination. This swelling could reach up to 10 cm or more in diameter and may be associated with pain and usually progressively reduces and disappears within 6 weeks after vaccination.
There may be a common transient slight increase in body temperature (1.5°C at most) lasting up to 3 days after vaccination.
Anaphylactic-type reactions may very rarely occur after vaccination. In such cases appropriate symptomatic treatment should be administered.

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

Subcutaneous use

Vaccine dose – 2ml

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 PERIOD(S)

Zero days

11. SPECIAL STORAGE PRECAUTIONS

Store and transport in a refrigerator (2°C to 8°C)
Do not freeze. Protect from light.
Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.
Shelf-life after first opening the immediate packaging: 10 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only.

Special precautions for use in animals:
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.

Use during 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.

Overdose:
No adverse effects other than those mentioned in section 6 (Adverse Reactions) were observed.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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

<15. OTHER INFORMATION>

Prescription only medication (Exempt) POM-(E)

VPA 22715/002/001

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 10ml, 10 x 10ml, 1 x 50 ml 1 x 100ml

Not all pack sizes may be marketed.

Approved 17 December 2020