1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pneumovac Plus suspension for injection for cattle

2. QUALITATIVE AND QUANTITATIVE 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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.2 mg
Formaldehyde 35% solution	- max 1 mg
Sodium chloride	
Water for injections	

Rosy liquid with sediment.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

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.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Very common (>1 animal / 10 animals treated):	Injection site swelling,[1] Injection site pain[2]
Common (1 to 10 animals / 100 animals treated):	Elevated temperature[3]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactic-type reactions[4]

[1] Up to 10 cm or more in diameter, and usually progressively reduces. Disappears within 6 weeks after vaccination.
[2] Associated with injection site swelling.
[3] Increase in body temperature (1.5 °C at most) lasting up to 3 days after vaccination.
[4] Appropriate symptomatic treatment should be administered.

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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Do not use during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

Subcutaneous use
Vaccine dose – 2 ml
Warm the vaccine before use to a temperature of 15 °C to 25 °C.

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.

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

No adverse events other than those mentioned in section 3.6 were observed.

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

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code :

QI02AL04

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 10 hours.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C to 8 °C).

Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

The vaccine is filled in glass vials:
Hydrolytic type I 10 ml vials containing 10 ml (5 doses) Hydrolytic type II 50 ml vials containing 50 ml (25 doses) 100 ml vials containing 100 ml (50 doses)

Also in plastic vials:
15 ml vials containing 10 ml (5 doses) 60 ml vials containing 50 ml (25 doses) 120 ml vials containing 100 ml (50 doses)

All containers are closed with chlorobutyl rubber stoppers and secured with aluminium seals.

The product is delivered as follows:
1 x 10 ml, 1 x 50 ml, 1 x 100 ml in cardboard boxes
10 x 10 ml in a transparent plastic box with cover or packed in a cardboard box

Not all pack sizes may be marketed.

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.

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

Animal Health Distributors Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22715/002/001

8. DATE OF FIRST AUTHORISATION

08/01/2021

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

10/04/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

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).