Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Pneumovac Plus suspension for injection for cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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 1mg

For the full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Suspension for injection. Rosy liquid with sediment

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

i) 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.

ii) 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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

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

<u>Primary vaccination:</u>
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.

<u>Revaccination:</u>
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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse effects other than those mentioned in section 4.6 (Adverse Reactions) were observed.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group:
Immunologicals for Bovidae; inactivated viral and inactivated bacterial vaccines for cattle.
ATC Vet Code: QI02AL04

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Thiomersal
Formaldehyde 35% solution
Quillaja saponin (Quil A)
Sodium Chloride
Water for Injection

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product

6.3 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

6.4 Special precautions for storage

Store and transport in a refrigerator (2°C to 8°C)
Do not freeze. Protect from light.

6.5 Nature and composition of immediate packaging

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

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

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

The product is delivered as follows:
10 x 10ml in a transparent plastic box with cover
1 x 10ml, 1 x 50ml, 1 x 100ml in cardboard boxes
Carton for mass packaging
10 x 10 ml

Each package contains an approved Package Leaflet

Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA22715/002/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 January 2021

10 DATE OF REVISION OF THE TEXT