

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BOVALTO Respi 4 suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (2 ml) contains:

Active substances:

Inactivated bovine respiratory syncytial virus, strain BIO-24RP* \geq 1
Inactivated bovine parainfluenza 3 virus, strain BIO-23.....RP* \geq 1
Inactivated bovine viral diarrhoea virus, strain BIO-25RP* \geq 1
Inactivated *Mannheimia haemolytica*, serotype A1 strain DSM 5283.....RP* \geq 1

* Relative potency (RP) 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
Formaldehyde 1.0 mg at most.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

Appearance: pinkish 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 in the absence of maternally derived antibodies against:

- parainfluenza 3 virus, to reduce virus excretion due to infection
- bovine respiratory syncytial virus, to reduce virus excretion due to infection

- bovine viral diarrhoea virus, to reduce virus excretion due to infection
- *Mannheimia haemolytica* serotype A1, to reduce clinical signs and lung lesions.

Onset of immunity: 3 weeks
Duration of immunity: 6 months

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals:

Safety and efficacy studies were performed in sero-negative calves. The efficacy of the vaccination has not been demonstrated in 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.

4.6 Adverse reactions (frequency and seriousness)

Cattle:

Very common (>1 animal / 10 animals treated):	Injection site swelling*
Common (1 to 10 animals / 100 animals treated):	Hyperthermia**
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylactic-type reactions*** Injection site pain ****

* 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.

** Transient and slight, higher after the second injection (1.5°C at most) lasting up to 3 days after vaccination.

*** Appropriate symptomatic treatment should be administered.

**** Associated with injection site swelling.

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 its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

4.8 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.

4.9 Amount(s) to be administered and administration route

Subcutaneous use.

Dose: 2 ml administered subcutaneously.

Warm before use to a temperature of 15 °C to 25 °C and shake the contents of the bottle.

Primary vaccination

Calves from non-immune dams: two doses three 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 one dose six months after completion of the primary vaccination scheme.

The efficacy of revaccination was demonstrated by measurement of the serological response and has not been assessed by challenge.

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

No adverse events other than those mentioned in section 4.6 (Adverse events) were observed after the administration of a 2-fold overdose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Bovidae; inactivated viral and bacterial vaccines for cattle.

ATCvet code: QI02AL

The vaccine induces an active immunity against bovine respiratory syncytial virus, parainfluenza 3 virus, bovine viral diarrhoea virus and *Mannheimia haemolytica*.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Thiomersal
Formaldehyde
Quillaja saponin (Quil A)
Sodium chloride
Water for injections

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 refrigerated (2 °C – 8 °C).
Do not freeze. Protect from light.

6.5 Nature and composition of immediate packaging

Type I glass bottle of 10 ml with chlorobutyl elastomer closure (5 doses)
Type II glass bottle of 50 or 100 ml with chlorobutyl elastomer closure (25 or 50 doses)

Translucent HDPE plastic bottle of 10, 50 or 100 ml with chlorobutyl elastomer closure (5, 25 or 50 doses).

Bottle is secured with an aluminium cap.

Cardboard box of 1 bottle of 5 doses (10 ml)
Covered plastic box of 10 bottles of 5 doses (10 x 10 ml)
Cardboard box of 1 bottle of 25 doses (50 ml)
Cardboard box of 1 bottle of 50 doses (100 ml)

Cardboard box of 10 bottles of 5 doses (10 x 10 ml)

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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

Boehringer Ingelheim Animal Health UK Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 08327/ 5011

9. DATE OF FIRST AUTHORISATION

17 February 2016

10. DATE OF REVISION OF THE TEXT

August 2023

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.



Approved: 11 August 2023