1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BOVALTO Respi 3 suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (2 ml) contains:

Active substances:
Inactivated bovine respiratory syncytial virus, strain BIO-24 ..... RP* ≥ 1
Inactivated bovine parainfluenza 3 virus, strain BIO-23 ..... RP* ≥ 1
Inactivated *Mannheimia haemolytica*, serotype A1 strain DSM 5283 ..... RP* ≥ 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:

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	1.0 mg at most
Sodium chloride	
Water for injections	

Appearance: pinkish 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 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,
- *Mannheimia haemolytica* serotype A1, to reduce clinical signs and lung lesions.

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

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:
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.

3.6 Adverse events

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.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used 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 route and dosage

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.

Prim ary vacc inati on
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.

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

No adverse events other than those mentioned in section 3.6 (Adverse events) were observed after the administration of a 2-fold overdose.

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: QI02AL

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

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

5.4 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.

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

Zoetis Belgium S.A.,

7. MARKETING AUTHORISATION NUMBER(S)

VPA10387/006/001

8. DATE OF FIRST AUTHORISATION

07/02/2014

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

28/06/2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

IE: 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).