SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imuresp RP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of Imuresp RP contains the following:

Active substances:
Live attenuated virus of Infectious Bovine Rhinotracheitis (IBR) strain ts RLB 106:
minimum: $10^{5.5}$ $CCID_{50}$ per dose

Live attenuated virus of Parainfluenza type 3 (PI3) strain ts RLB 103:
minimum: $10^{5.2}$ $CCID_{50}$ per dose

For full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Lyophilised nasal powder with sterile diluent for reconstitution.

4. CLINICAL PARTICULARS

4.1 Target species

Calves and growing cattle.

4.2 Indications for use, specifying the target species

For active immunisation to reduce the clinical signs and viral shedding associated with Infections Bovine Rhinotracheitis (Bovine Herpesvirus type I) and for active immunisation to reduce PI3 viral shedding from infected animals.

Onset of immunity occurs by 4 days after vaccination.

Duration of protection has been demonstrated for up to 6 months after vaccination for the Infections Bovine Rhinotracheitis virus component and for up to 5 months after vaccination for the Parainfluenza type 3 virus component.

4.3 Contraindications

Do not vaccinate unhealthy animals.

4.4 Special warnings for each target species

Do not vaccinate animals for at least one month after cessation of corticosteroid treatment.
If an anaphylactic response occurs, institute appropriate antihistaminic therapy.
The vaccine viruses may spread to susceptible contact animals, which may cause these animals to seroconvert to IBR virus and/or Pi3 virus. It is therefore recommended to vaccinate all animals housed together at the same time. Unvaccinated pregnant animals should not be housed with recently vaccinated stock.

4.5 Special precautions for use

i) Special precautions for use in animals

None.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

No special precautions are needed for other livestock, vaccinators or stock handlers.

4.6 Adverse reactions (frequency and seriousness)

Vaccination may be followed by pyrexia, which may last from 1 to 4 days and will usually resolve without medication.

4.7 Use during pregnancy, lactation or lay

This vaccine is not recommended for use in pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other except Rispoval™ RS. 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

Dosage and route of administration:
Reconstitute the entire constituents of the vaccine vial with the whole sterile diluent using the needle and the syringe provided. For each animal, withdraw 2 ml of reconstituted vaccine, substitute nasal applicator for the needle and instil 2 ml into one nostril, holding head up gently but firmly. One applicator is supplied for every dose.
Take care to avoid the introduction of contamination while reconstituting and withdrawing vaccine.
The vaccine should be used immediately after reconstitution and not stored.

Vaccination programme:

Animals older than 10 weeks of age
A single dose of vaccine should be administered.

Animals from 3 weeks to 10 weeks of age
Since maternal antibodies may interfere with the development of immunity in very young calves it is advisable to give two doses of vaccine, at least 14 days apart. The first dose may be given at any time from 3 weeks of age. The second dose should not be given until at least 10 weeks of age.

Revaccination
In order to maintain immunity, animals should be revaccinated every 6 months with a single dose of vaccine.

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

No post vaccination reactions other than the ones quoted above under point 4.6 have been observed with a ten times overdose of Imuresp RP.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against Infectious Bovine Rhinotracheitis virus (Bovine Herpesvirus type 1) and Parainfluenza Type 3 virus infections.

ATC VET CODE QI02AD06

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Neomycin
Gentamycin

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product except the diluent supplied.

6.3 Shelf life

2 years.
Reconstituted vaccine should be used immediately.

6.4 Special precautions for storage

Store and transport between +2°C and +8°C away from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

Cardboard carton containing a 5 dose type I glass vial closed with a rubber stopper and sealed with an aluminium cap and a type I hydrolytic glass vial containing 10 ml of diluent. Also supplied in a carton containing 20 x 5 dose vials, supplied together with a carton containing 20 x 10ml vials of diluent. Needles and syringes for reconstitution and nasal applicators for vaccination are provided in separate accessory packs.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

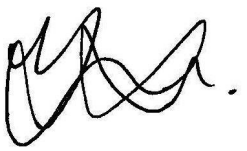
Vm 42058/4072

9. DATE OF FIRST AUTHORISATION

07 October 2005

10. DATE OF REVISION OF THE TEXT

May 2020



Approved: 01 May 2020