ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Imuresp RP – Carton
1x 10 ml (5 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imuresp RP

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Vaccine containing IBR and Pi3

COMPOSITION:

Freeze-dried fraction:
- Live attenuated Parainfluenza type 3 (Pi3) virus, strain ts RLB 103, minimum $10^{5.2}$ $CCID_{50}$ per dose.
- Live attenuated Infectious Bovine Rhinotracheitis (IBR) virus, strain ts RLB 106, minimum $10^{5.5}$ $CCID_{50}$ per dose.

Diluent:
- Water for injection.
- Sodium chloride, 18mg per 2 ml

3. PHARMACEUTICAL FORM

Lyophilised nasal powder with sterile diluent for reconstitution.

4. PACKAGE SIZE

1 x 5 dose freeze-dried vial + 1 x 5 dose diluent (10 ml)
1 x 10 ml (5 doses)

5. TARGET SPECIES

For cattle

6. INDICATION(S)

INDICATIONS: For the active immunisation of calves and growing cattle to reduce the clinical signs and viral shedding associated with IBR and to reduce Pi3 viral shedding from infected animals.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DOSE: 2ml.
ROUTE: Intranasal. Reconstitute the entire contents of the freeze-dried vial with the entire contents of the diluent vial.

VACCINATION PROGRAMME:
Animals older than 10 weeks of age: A single dose of vaccine should be administered.
Animals from 3 to 10 weeks of age: Two doses of vaccine at least 14 days apart. Animals should be revaccinated every 6 months in order to maintain immunity.

8. WITHDRAWAL PERIOD

WITHDRAWAL PERIOD: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Consult the package leaflet for further information, contra-indications and warnings etc.

10. EXPIRY DATE

EXP date:
Reconstituted vaccine should be used immediately.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Consult the package leaflet for further information, contra-indications and warnings etc.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

POM-V
To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4072

17. MANUFACTURER'S BATCH NUMBER

Lot No:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Imuresp RP – Carton
20x 10 ml (5 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imuresp RP

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Vaccine containing IBR and Pi3

COMPOSITION:

Freeze-dried fraction:
- Live attenuated Parainfluenza type 3 (Pi3) virus, strain ts RLB 103, minimum $10^{5.2}$ $CCID_{50}$ per dose.
- Live attenuated Infectious Bovine Rhinotracheitis (IBR) virus, strain ts RLB 106, minimum $10^{5.5}$ $CCID_{50}$ per dose.

3. PHARMACEUTICAL FORM

Lyophilised nasal powder with sterile diluent for reconstitution.

4. PACKAGE SIZE

20 x 5 dose freeze-dried vials

5. TARGET SPECIES

For cattle

6. INDICATION(S)

INDICATIONS: For the active immunisation of calves and growing cattle to reduce the clinical signs and viral shedding associated with IBR and to reduce Pi3 viral shedding from infected animals.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

DOSE: 2ml.
ROUTE: Intranasal. Reconstitute the entire contents of the freeze-dried vial with the entire contents of the diluent vial.

VACCINATION PROGRAMME:
Animals older than 10 weeks of age: A single dose of vaccine should be administered.
Animals from 3 to 10 weeks of age: Two doses of vaccine at least 14 days apart.

Animals should be revaccinated every 6 months in order to maintain immunity.

8. WITHDRAWAL PERIOD

WITHDRAWAL PERIOD: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Consult the package leaflet for further information, contra-indications and warnings etc.

10. EXPIRY DATE

Expiry date:
Reconstituted vaccine should be used immediately.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Consult the package leaflet for further information, contra-indications and warnings etc.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

POM-V
To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4072

17. MANUFACTURER'S BATCH NUMBER

Batch No:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Imuresp RP – Vial label
5 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imuresp RP
For cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

COMPOSITION:
Freeze-dried fraction:
- Live attenuated Parainfluenza type 3 (Pi3) virus, strain ts RLB 103, minimum $10^{5.2}$ $CCID_{50}$ per dose.
- Live attenuated Infectious Bovine Rhinotracheitis (IBR) virus, strain ts RLB 106, minimum $10^{5.5}$ $CCID_{50}$ per dose.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 doses

4. ROUTE(S) OF ADMINISTRATION

For intranasal administration.

5. WITHDRAWAL PERIOD

Withdrawal period: zero days

6. BATCH NUMBER

Lot No:

7. EXPIRY DATE

Exp date:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.
Keep out of reach of children
Store and transport between +2°C and +8°C away from light. Do not freeze.
For full instructions see package leaflet.

MA Holder:
Zoetis UK Limited, Surrey

To be supplied only on veterinary prescription.
Vm 42058/4072 POM-V

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Imuresp RP

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imuresp RP

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

A freeze-dried pellet, each dose containing live Parainfluenza type 3 (Pi3) virus, strain ts RLB 103, minimum $10^{5.2}$ $CCID_{50}$ and live attenuated Infectious Bovine Rhinotracheitis (IBR) virus, strain ts RLB 106, minimum $10^{5.5}$ $CCID_{50}$ supplied together with a vial of sterile diluent for reconstitution. Also contains traces of neomycin sulphate and gentamycin sulphate (not exceeding 25 µg).
*$CCID_{50}$ = Cell Culture Infectious Dose 50

4. INDICATION(S)

For the active immunisation of calves and growing cattle to reduce the clinical signs and viral shedding associated with Infections Bovine Rhinotracheitis (Bovine Herpesvirus type I) and 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 IBR component and for up to 5 months after vaccination for the Pi3 component.

5. CONTRAINDICATIONS

Do not vaccinate unhealthy animals or pregnant animals.

6. ADVERSE REACTIONS

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

7. TARGET SPECIES

Calves and growing cattle.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Reconstitute the entire contents of the vaccine with the entire contents of the sterile diluent, using the needle and syringe provided. For each animal, withdraw 2ml of reconstituted vaccine, substitute the nasal applicator for the needle and administer 2ml 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.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Store and transport vaccine between +2°C and +8°C away from light. Do not freeze.
Keep out of reach of children.

12. SPECIAL WARNING(S)

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.
No special precautions are needed for other livestock, vaccinators or stock handlers.
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.
Do not mix with any other veterinary medicinal product except the diluent supplied.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

May 2020

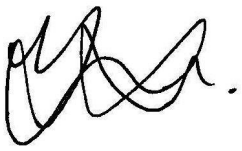
15. OTHER INFORMATION

For animal treatment only.

LEGAL CATEGORY POM-V To be supplied only on veterinary prescription.

PACKAGE QUANTITIES
Cardboard carton containing a 5 dose vial together with a 10 ml vial of sterile diluent. Also supplied in a cardboard carton containing 20 x 5 dose vials supplied together with 20 x 10ml vials of sterile diluent. Not all pack sizes may be marketed. Needles and syringes for reconstitution and nasal applicators for vaccination are provided in separate accessory packs.

MARKETING AUTHORSATION NUMBER
Vm 42058/4072



Approved: 01 May 2020