SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac Relera concentrate for dip suspension or suspension for injection for rainbow trout

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of vaccine (concentrate) contains:

Active substances:
Inactivated cells of *Yersinia ruckeri* (Hagerman type 1 strain) inducing ≥ 75% RPS*
Inactivated cells of *Yersinia ruckeri* (EX5 biotype strain) inducing ≥ 75% RPS*

*RPS: relative percentage of survival in rainbow trout

Excipients:
Residual formaldehyde: ≤ 0.05% (w/v)

For the full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Concentrate for dip suspension or suspension for injection.
Suspension in brown aqueous liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Rainbow trout (*Oncorhynchus mykiss*).

4.2 Indications for use, specifying the target species

Active immunization against Enteric Redmouth disease (ERM) to reduce mortality caused by Hagerman type 1 and EX5 biotype strains of Yersinia ruckeri.

Immersion route:
Onset of immunity: 336 degree days (28 days at 12°C) for Hagerman type 1 and for EX5 biotype.
Duration of immunity:
6 months (205 days at 12°C) for the Hagerman type 1.
4 months (133 days at 12°C) for the EX5 biotype.
Please note that the level of protection against the EX5 biotype wanes during the indicated period.

Injection route (only for booster vaccination):
Duration of immunity: Immunity has not been studied beyond 28 days (336 degree days).

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.
Do not vaccinate if the water temperature is below 12°C.

The minimum weights for fish before vaccination must be respected (see section 4.9 of the SPC).

4.5 Special precautions for use

Special precautions for use in animals
Avoid stress at the time of the handling of fish, as well as temperature variations, in particular between the vaccine suspension and the water of the holding area.

Special precautions to be taken by the persons administering the veterinary medicinal product to animals
Protective equipment should be used to avoid self injection.
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)

Injection administration very commonly induces very slight adhesions (Speilberg score 1) at the site of injection, which may persist for 7 weeks but are normally no longer observed 3 months after injection.

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

Fertility:
Do not administer to broodstock or fish intended as broodstock.

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 Amounts to be administered and administration route

Primary vaccination should be by the immersion route only. In the event that a booster vaccination is required to extend the duration of immunity for a further 28 days then the injection route should be used.

When administering by immersion, dilute the contents immediately after opening the container, and use diluted vaccine immediately.
The development of protective immunity is dependent on the water temperature.
Shake the bottle before use.

Primary vaccination by immersion (Fish of at least 5 g)
Dilute the contents of the bottle (1 litre) in 9 litres of hatchery water, clean and suitably oxygenated.
Place the fish into batches and immerse for 30 seconds in the diluted vaccine.
A litre of vaccine (making 10 litres of diluted vaccine) allows the vaccination of a maximum of 100 kg of fish.

Booster vaccination by injection (Fish of at least 12 g)
The vaccine must be administered using a multi-dose injection applicator incorporating a mechanism to prevent flush-back. This applies equally to hand-held and automatic systems.

The product is administered by intra-peritoneal injection in the ventral area, just anterior to the pelvic fins. The dose is 0.1 ml per fish.
The fish should be anaesthetised prior to vaccination.

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

No adverse effects have been noted following a double dose of vaccine by immersion or injection other than those mentioned in section 4.6.

4.11 Withdrawal period(s)

Zero degree days.

5. IMMUNOLOGICAL PROPERTIES

The vaccine induces active immunity against enteric redmouth disease caused by Yersinia ruckeri, Hagerman type 1 strain and the EX5 biotype.

Pharmacotherapeutic group: Inactivated bacterial vaccines (including mycoplasma, toxoid and chlamydia), Yersinia.
ATC-vet code QI10BB03.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Residual formaldehyde
Sodium chloride
Purified water

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: use within 5 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

The product is supplied in 1000 ml crimp-sealed bottles: high-density polyethylene bottles, red bromobutyl stoppers, aluminium cap.

Pack size: 1000 ml (10,000 doses).

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 material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V., represented by the national companies in the Member States
Wim de Körverstraat
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}
Date of last renewal: {DD/MM/YYYY}

10. DATE OF REVISION OF THE TEXT

{MM/DD/YYYY}

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

PACKAGE LEAFLET

PACKAGE LEAFLET/LABEL[1]:
AquaVac Relera concentrate for dip suspension or suspension for injection for rainbow trout

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

Marketing authorisation holder:
Intervet International B.V., represented by the national companies in the Member States
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Manufacturer responsible for batch release: [2]
Intervet UK, Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire, MK7 7AJ
United Kingdom

Merck Sharp & Dohme Animal Health S.L.
Poligono Industrial El Montalvo I
C/Zeppelin 6, Parcela 38,
37008 Carbajosa de La Sagrada (Salamanca)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac Relera concentrate for dip suspension or suspension for injection for rainbow trout

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

Each ml of vaccine (concentrate) contains:

Active substances:
Inactivated cells of *Yersinia ruckeri* (Hagerman type 1 strain) inducing ≥ 75% RPS*
Inactivated cells of *Yersinia ruckeri* (EX5 biotype strain) inducing ≥ 75% RPS*

*RPS: relative percentage of survival in rainbow trout

Excipients:
Residual formaldehyde: ≤ 0.05% (w/v)

4. INDICATION(S)

[1] This text will form the label for the product. There is no separate leaflet for this product. The text numbering is taken from the template for the package insert, and under 15 Other Information is given the additional information required by the label template.

[2] The printed package leaflet will state the name and address of the manufacturer responsible for the release of the concerned batch only.

Active immunization against Enteric Redmouth disease (ERM) to reduce mortality caused by Hagerman type 1 and EX5 biotype strains of *Yersinia ruckeri*.

Immersion route:
Onset of immunity: 336 degree days (28 days at 12°C) for Hagerman type 1 and for EX5 biotype.
Duration of immunity:
6 months (205 days at 12°C) for the Hagerman type 1.
4 months (133 days at 12°C) for the EX5 biotype.
Please note that the level of protection against the EX5 biotype wanes during the indicated period.

Injection route (only for booster vaccination):
Duration of immunity: Immunity has not been studied beyond 28 days (336 degree days).

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Injection administration very commonly induces very slight adhesions (Speilberg score 1) at the site of injection, which may persist for 7 weeks but are normally no longer observed 3 months after injection.

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 1but less than 10 animals in 100 animals treated)
- uncommon (more than 1but 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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Rainbow trout (*Oncorhynchus mykiss*).

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

Primary vaccination should be by the immersion route only. In the event that a booster vaccination is required to extend the duration of immunity for a further 28 days then the injection route should be used.

The development of protective immunity is dependent on the water temperature.

Shake the bottle before use.

Primary vaccination by immersion (Fish of least 5 g)
Dilute the contents of the bottle (1 litre) in 9 litres of hatchery water, clean and suitably oxygenated.
Place the fish into batches and immerse for 30 seconds in the diluted vaccine.
A litre of vaccine (making 10 litres of diluted vaccine) allows the vaccination of a maximum of 100 kg of fish.

Booster vaccination by injection (Fish of at least 12 g)

The product is administered by intra-peritoneal injection in the ventral area, just anterior to the pelvic fins. The dose is 0.1 ml per fish.
The fish should be anaesthetised prior to vaccination.

9. ADVICE ON CORRECT ADMINISTRATION

Primary vaccination by immersion: Dilute the contents immediately after opening the container, and use diluted vaccine immediately.

Booster vaccination by injection: The vaccine must be administered using a multi-dose injection applicator incorporating a mechanism to prevent flush-back. This applies equally to hand-held and automatic systems.
Careful injection technique is important to minimise adverse reactions.

10. WITHDRAWAL PERIOD(S)

Zero degree days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C - 8 °C).
Do not freeze.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

Shelf life after first opening the container: use within 5 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.
Do not vaccinate if the water temperature is below 12°C
The minimum weights for fish before vaccination must be respected.

Special precautions for use in animals:
Avoid stress at the time of the handling of fish, as well as temperature variations, in particular between the vaccine suspension and the water of the holding area.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Protective equipment should be used to avoid self- injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Fertility:
Do not administer to broodstock or fish intended as broodstock.

Interaction with other medicinal products and other form 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.

Overdose (symptoms, emergency procedures, antidotes):
No adverse effects have been noted following a double dose of vaccine by immersion or injection other than those mentioned in section "Adverse Reactions" of this leaflet.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

For animal treatment only.

Package size:	1000 ml
Pharmaceutical form:	Concentrate for dip suspension or suspension for injection
Marketing Authorisation number:	{as allocated by the Member State}

Batch	{number}
EXP	{month/year}