



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**

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***

Only vaccinate healthy fish.

Do not vaccinate if the water temperature is below 12°C.

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 can induce 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.

**4.7 Use during pregnancy, lactation or lay**

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 dependant 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.

**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.

ATC Vet Code QI10BB03

**1.1.1 6 PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

**Residual Formaldehyde, Sodium chloride**

**6.2 Incompatibilities**

Do not mix with any other vaccine/immunological product.

**6.3 Shelf life**

Shelf-life as packaged for sale: 2 years.

Vaccine should be used by injection within 5 hours of breaching the vial.

**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**

Nature of primary packaging

high-density polyethylene bottles, red bromobutyl stoppers, aluminium cap

Packages intended for sales

The product is supplied in 1000 ml crimp-sealed bottles.

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

Any unused vaccine should be disposed of in accordance with national requirements.

**7 MARKETING AUTHORISATION HOLDER**

Intervet International B.V.  
Wim de Körverstraat  
5831 AN Boxmeer  
The Netherlands

As represented by the national company

**8. MARKETING AUTHORISATION NUMBER**

**9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION**

**10. DATE OF REVISION OF TEXT**

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.