# 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

**Active ingredient**

| | |
|---|---|
| Inactivated cells of *Yersinia ruckeri* (Hagerman type 1 strain) | ≥ 75% RPS* |
| Inactivated cells of *Yersinia ruckeri* (EX5 biotype strain) | ≥ 75% RPS* |

**Excipient**

| | |
|---|---|
| Residual Formaldehyde | ≤ 0.05% w/v |

*RPS : relative percentage of survival in Rainbow Trout

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

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

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Residual Formaldehyde
Sodium chloride

### 6.2 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

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 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

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

## 8. MARKETING AUTHORISATION NUMBER

Vm 01708/4615

## 9. DATE OF FIRST AUTHORISATION

15 May 2009

## 10. DATE OF REVISION OF TEXT

June 2020

Approved: 10 June 2020