PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each 1 ml of vaccine (concentrate) contains:

Active substances:
Yersinia ruckeri serotype O1, biotype 1, strain Hagerman, inactivated, inducing ≥ 75% RPS*
Yersinia ruckeri serotype O1, biotype 2 (EX5), strain SP/07/04, inactivated, inducing ≥ 75% RPS*

*RPS: relative percentage of survival in rainbow trout

Suspension in brown aqueous liquid.

3. Target species

Rainbow trout (*Oncorhynchus mykiss*).

4. Indications for use

Active immunisation 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.

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

5. Contraindications

None.

6. Special warnings

Special warnings:
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 safe use in the target species:
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:
Personal protective equipment consisting of guarded needles or needle protectors should be worn when handling the veterinary medicinal product.
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 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.

Overdose:
No adverse effects have been noted following a double dose of vaccine by immersion or intraperitoneal injection
other than those mentioned in section "Adverse events" of this leaflet.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Rainbow trout (*Oncorhynchus mykiss*):

Very common (>1 animal / 10 animals treated):	Adhesion in fish[1].

[1] Very slight (Speilberg score 1) induced by injection administration at the site of injection, which may persist for 7 weeks but are normally no longer observed 3 months after injection.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

{< > to be adjusted nationally}

8. Dosage for each species, routes 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 intraperitoneal injection (Fish of at least 12 g)
The product is administered by intraperitoneal 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 intraperitoneal 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 periods

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. The expiry date refers to the last day of that month.

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or <household waste>.
{< > to be adjusted nationally}

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

{to be completed nationally}

Pack size:
1000 ml

15. Date on which the package leaflet was last revised

{MM/YYYY} {to be completed nationally}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and <manufacturer responsible for batch release><and contact details to report suspected adverse reactions>:
{< > to be adjusted nationally}

<Manufacturer responsible for batch release[1]>: {to be adjusted nationally if included in the above}
MSD Animal Health 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

<Local representatives and contact details to report suspected adverse reactions>:
{< > to be adjusted nationally}

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>
{< > to be adjusted nationally}

17. Other information

For animal treatment only.

{to be completed nationally}

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