B. PACKAGE LEAFLET

PACKAGE LEAFLET/LABEL*:
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:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release: †
MSD Animal Health UK Limited
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)

* 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.

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

4. INDICATION(S)

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

October 2020

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}