LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE*

Bottle (label)

** The label and leaflet are presented in a fold-out format. The label text of this section will appear twice in the packaging material ie. In the outermost face of the fold-out and the inner face in the closest contact of the bottle.*

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac ERM Concentrate for dip suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose contains:

Yersinia ruckeri, serotype O1, strain Hagerman, inactivated ≥ 75% RPS*
*RPS: relative percentage of survival in Rainbow Trout

3. PACKAGE SIZE

1000 ml

4. TARGET SPECIES

Rainbow trout (*Oncorhynchus mykiss)*

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Immersion use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero degree days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once diluted use within 5 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE".

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY".

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN".

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/3047

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

AquaVac ERM Concentrate for dip suspension for Rainbow Trout

2. Composition

Each dose contains:

Active substance:
Yersinia ruckeri, serotype O1, strain Hagerman, inactivated inducing ≥ 75% RPS*

*RPS: relative percentage of survival in Rainbow Trout

Yellowish-brown suspension.

3. Target species

Rainbow trout (*Oncorhynchus mykiss)*.

4. Indications for use

In Rainbow Trout of 2 grams weight or over: Active immunisation against Enteric Redmouth disease (ERM) to reduce mortality caused by the Hagerman Type I strain of *Yersinia ruckeri.*

Onset of immunity: 28 days at a water temperature of 12 °C (336 degree days are required for the development of full immunity). The time for development of protective immunity will depend on water temperature.

Duration of immunity: 78 days (shown under laboratory conditions).
Under field conditions, protection may be expected for at least 6 months. A booster vaccination administered 4 months after primary vaccination may induce a better level of protection.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
During vaccination, the temperature of the diluted vaccine should not differ from the water temperature in the holding area by more than ± 5 °C.

Fish should be subjected to the minimum of manipulations such as sorting and transportation during the periods shortly before and after vaccination.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Personal protective equipment consisting of rubber gloves should be worn when handling the veterinary medicinal product.

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

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

7. Adverse events

None known.

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:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

The product is administered to Rainbow Trout of not less than 2 grams in weight by immersion for 30 seconds in vaccine diluted 1 in 10 with hatchery water. 1 litre of vaccine, diluted to 10 litres in total, is sufficient to vaccinate 100 kg of fish.

9. Advice on correct administration

Fish may be vaccinated in batches. The size of each batch should be appropriate to the volume of diluted vaccine available and to the size of the fish. The diluted vaccine should be oxygenated, if necessary, between vaccinations of individual batches.

10. Withdrawal periods

Zero degree days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store in a refrigerator (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 dilution according to directions: 5 hours.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater

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

Vm 01708/3047

Pack size:
1000 ml

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:

Marketing authorisation holder
MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ

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

Contact details to report suspected adverse reactions
MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

17. Other information

For animal treatment only.

{to be completed nationally}

POM-VPS

Gavin Hall
Approved: 12 December 2024

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