Acuipharma
Aquaculture health solutions

Combined autovaccine against:

Lactococcus garvieae

Yersinia ruckeri

Aeromonas salmonicida subsp. *salmonicida*

Autovaccine for veterinary use / Prescription-only veterinary medicinal product

Prevention and reduction of morbidity and mortality due to lactococcosis, yersiniosis and furunculosis in rainbow trout

DESCRIPTION

Suspension of formalin-inactivated bacteria from: *Lactococcus garvieae, Yersinia ruckeri and Aeromonas salmonicida* subsp. *salmonicida.* Contains a natural adjuvant. This autovaccine has been designed to be administered to rainbow trout by intraperitoneal injection. The bacterial strains come from the applicable fish farm. This autovaccine has been shown to be effective in the prevention and reduction of morbidity and mortality due to lactococcosis, yersiniosis and furunculosis in farmed rainbow trout (O*ncorhynchus mykiss*).

INDICATIONS FOR USE

At the time of vaccination, the animals must be healthy and disease free, as sick or weak animals may not develop adequate immunity. The fish must have a minimum weight of 15 grams. The fish should not be subject to stress for 4 to 5 days prior to and 15 days after vaccination (including selections, transfers, baths, etc.).
Immunity is established in rainbow trout 28 days after vaccination, the duration of immunity conferred depends on the facilities and is demonstrated in the laboratory and in the field to be over 9 months post-vaccination.
The vaccination temperature should be equal to or slightly below the optimum farming temperature.

The waiting time is 500 degrees-day.

DOSAGE

The autovaccine should be administered at a dose of 0.1 ml per fish by intraperitoneal injection.

ADMINISTRATION

Before vaccination, ensure that all material (nets, buckets and other equipment) is thoroughly cleaned and properly disinfected and rinsed before use. To reduce stress, it is recommended that the animals are not fed at least 24 hours prior to vaccination.
The autovaccine against *Lactococcus garvieae, Yersinia ruckeri and Aeromonas salmonicida* subsp. *salmonicida* is administered by intraperitoneal injection. The injection site of the needle into the fish is in the ventral midline, in front of the pelvic fins. Taking as a unit the length of the fins, it is generally recommended at a distance equivalent to 0.5 to 1.5 times the length of the fins, counting from the end of the bone of the pelvic fin to the head. The needle should be at an angle of about 45°, traversing the abdominal wall, without touching internal organs.
During the immersion anaesthesia process, monitor the oxygen level. The temperature of the solution must be the same as that of the facilities. The water in the facilities must have a minimum temperature of 8°C, and must be kept above this temperature for at least 15 days after vaccination. Each infusion set will be used with a new autovaccine container to avoid cross contamination.

STORAGE CONDITIONS

This autovaccine must be kept in the original packaging and properly sealed. Store at a temperature between +2°C and 8°C. Do not freeze.

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NATURE AND CONTENTS OF PRIMARY PACKAGING

250-ml and 500-ml sterile polypropylene bottles with serum stoppers and aluminium blister pack.

PRECAUTIONS and WARNINGS

1. ONLY VACCINATE HEALTHY ANIMALS. Simultaneously suffering a pathology at the time of vaccination or adverse environmental conditions can lead to complications and reduce the effectiveness of the autovaccine.
2. INTERACTIONS WITH OTHER MEDICINES HAVE NOT BEEN REPORTED. No information is available on the safety and efficacy of the use of this vaccine with any other veterinary medicinal product. The decision to use this vaccine before or after the administration of any other veterinary medicinal product should be made on a case-by-case basis.
3. SHAKE VIGOROUSLY BEFORE USE AND USE IMMEDIATELY AFTER OPENING THE PACK.
4. ONCE OPEN DO NOT STORE OR REUSE THE VACCINE. The autovaccine is prepared and designed to be used in a single application. Use uninterruptedly once content has been extracted. Once the container is open, it should be used in the same day.
5. ONLY ADMINISTER THE AUTOVACCINE AS INDICATED. Any change in the recommended dose may render the product ineffective.
6. WHEN THE VACCINATION PROCESS IS COMPLETE, DISPOSE OF ANY UNUSED VETERINARY MEDICINAL PRODUCTS OR THEIR RESIDUES IN COMPLIANCE WITH EACH COUNTRY'S REGULATIONS.
7. CAUTION WHEN HANDLING Avoid contact of the vaccine with the operator's skin and mucous membranes. Wash hands thoroughly after using the vaccine. In case of accident, rinse thoroughly with running water. For use by injection use gloves to protect against any skin-piercing. IF ACCIDENTAL SELF-INJECTION OCCURS, SEEK MEDICAL ADVICE IMMEDIATELY, SHOWING THE INFORMATION SHEET OR THE LABEL AND CONTACT:

   Acuipharma: Tel: +34 943 94 21 19 / Mobile: +34 693 72 73 55
8. Acuipharma should be immediately informed of ANY ADVERSE OR UNUSUAL EFFECTS ASSOCIATED with the use of the autovaccine (contact details in point 7).
9. THIS AUTOVACCINE IS ONLY FOR USE IN *ANIMALS*.

WARNING

The autovaccine against *L. garvieae*, *Y. ruckeri* and *Aeromonas salmonicida* subsp. *salmonicida* has been subjected to strict potency, safety and purity tests and meets the requirements established by the WHO Good Manufacturing Practice. It is designed to effectively stimulate immunity when used as described. Users should be aware that response to the product depends on many factors, including, but not limited to: storage and handling conditions by the user, vaccine administration method, fish health and sensitivity, environmental conditions after vaccination. Therefore, the guidelines should be carefully followed to ensure safe use and optimum performance.

The autovaccine against *L. garvieae*, *Y. ruckeri* and *Aeromonas salmonicida* subsp. *salmonicida* is not dangerous if used according to the instructions, and poses no risk to the health of healthy people.

Records

The user is advised to keep a written record of the vaccination, including *information about the vaccine* (amount, batch number, expiration date and supplier); *information on the target species* (species, batch number, pool number, population, age, average size and total weight of the vaccinated animals); *information about the vaccination* (veterinarian in charge, name of the operator administering the vaccine, date and time of vaccination, water temperature and environmental conditions, as well as *observations* on the general health of the animals at the time of vaccination and any unusual reactions or conditions observed.

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Registration number of the centre producing autovaccines for veterinary use: 20AV-UV43

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