Acuipharma
Aquaculture health solutions

Combined autovaccine against:

Photobacterium damselae subsp. *piscicida*
Vibrio anguillarum
Aeromonas salmonicida subsp. *salmonicida*

Autovaccine for veterinary use / Prescription-only veterinary medicinal product

Prevention and reduction of morbidity and mortality due to pasteurellosis , vibriosis and furunculosis in European sea bass and gilt-head bream

DESCRIPTION

Suspension of formalin-inactivated bacteria: *Photobacterium damselae* subsp. *piscicida, Vibrio anguillarum and Aeromonas salmonicida* subsp. *salmonicida.* Contains a natural adjuvant. This autovaccine has been designed to be administered to European sea bass and/or gilt-head bream by intraperitoneal injection. The bacterial strains come from the applicable fish farm. The autovaccine against *Photobacterium damselae* subsp. *piscicida, Vibrio anguillarum and Aeromonas salmonicida* subsp. *salmonicida* has been shown to be effective in the prevention and reduction of morbidity and mortality due to pasteurellosis, vibriosis and furunculosis in European sea bass (*Dicentrarchus labrax*) and gilt-head bream (*Sparus aurata*).

INDICATIONS FOR USE

This autovaccine is indicated to prevent diseases caused by the bacteria *Photobacterium damselae* subsp. *piscicida, Vibrio anguillarum and Aeromonas salmonicida* subsp. *salmonicida* in European sea bass and gilt-head bream. 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 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 28 days after vaccination. The vaccination temperature should be equal to or slightly below the optimum farming temperature.

The waiting time is 500 degrees-day.

VACCINATION PROGRAM

This autovaccine is part of a complete vaccination protocol for European sea bass and gilt-head bream as protection against pasteurellosis, vibriosis and furunculosis. Prior to use, breeders are advised to consult with their veterinarians and other responsible professionals involved in the fish's health. It is recommended to apply two short baths at approximately 1 and 3 grams, plus an intraperitoneal injection from 15 grams.

DOSAGE

Administration by immersion: The dosage of the autovaccine against *Photobacterium damselae* subsp. *piscicida, Vibrio anguillarum and Aeromonas salmonicida* subsp. *salmonicida* is based on the total weight of the animals and the volume of water in which they are vaccinated. One litre of this autovaccine is sufficient to vaccinate 100 kg of biomass in a short bath.

Administration by intraperitoneal injection: dose of 0.1 ml per fish. One litre of this autovaccine is sufficient to vaccinate 10,000 doses.

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.

Administration by immersion in short bath: Place the fish in the vaccine solution in a proportion of 1:10 (1 litre of autovaccine in 9 litres of water of the facilities) suitably oxygenated, in a bath lasting 1 minute. In each immersion do not exceed 0.5 kg of fish per litre of vaccine solution (5 kg of fish in 10 L of vaccine solution). Discard the vaccine solution after 20 immersions. To prepare the vaccine solution, use the water that the fish are usually bathed in. The temperature of the vaccine solution must be the same as that of the facilities. Monitor the oxygen level of the vaccine solution.

Administration by intraperitoneal injection: This autovaccine is administered by intraperitoneal injection in the central part of the abdomen between the pelvic fins. The needle should be at an angle of about 45°, traversing the abdominal wall, without touching internal organs. The minimum vaccination size is 15 grams. During the immersion anaesthesia process, monitor the oxygen level. 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.

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 or 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. Once the container is open, it should be used in the same day. Use uninterruptedly once content has been extracted.
5. ONLY ADMINISTER THE AUTOVACCINE AS INDICATED. Do not vaccinate more fish than indicated. Any change in recommended dose/dilution may render the product ineffective.
6. CALCULATING THE NUMBER OF ANIMALS TO VACCINATE. When the autovaccine is administered per bath, the dose refers to biomass (total weight), so it is important to keep in mind the maximum number of fish to be vaccinated according to the size of the vaccine solution, to ensure the efficacy and safety of the vaccine. DO NOT VACCINATE MORE FISH THAN INDICATED.
7. DURING THE AWAKENING PROCESS, DUE TO THE LACK OF MOBILITY OF THE OPERCULUM, IT IS IMPORTANT THAT THE OXYGEN LEVEL IS IN OVERSATURATION OF AROUND 10 ppm, AND TO ISOLATE FISH THAT ARE WAKING UP FROM OTHERS THAT ARE ALREADY AWAKE AND ACTIVE , TO PROTECT THEM FROM POSSIBLE ATTACKS.
8. ONCE THE CONTAINER IS OPEN, IT SHOULD BE USED IN THE SAME DAY. USE UNINTERRUPTEDLY ONCE CONTENT HAS BEEN EXTRACTED.
9. WHEN THE VACCINATION PROCESS IS COMPLETE, DISPOSE OF ANY UNUSED VETERINARY MEDICINAL PRODUCTS OR THEIR RESIDUES IN COMPLIANCE WITH EACH COUNTRY'S REGULATIONS.
10. 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
11. ACUIPHARMA SHOULD BE IMMEDIATELY INFORMED of ANY ADVERSE OR UNUSUAL EFFECTS ASSOCIATED with the use of the autovaccine (contact details in point 9).
12. THIS AUTOVACCINE IS ONLY FOR USE IN ANIMALS.

WARNING

The autovaccine against *Photobacterium damselae* subsp*. piscicida, Vibrio anguillarum 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.

This autovaccine 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.

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

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