1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA DIP Vib concentrate for dip suspension for sea bass

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:
Inactivated *Listonella anguillarum (Vibrio anguillarum)* serotype O1, strain AL 112 RPS[1] ≥ 75

[1] RPS (Relative Percentage Survival) is based on results from challenge studies and calculated according to the following quotation: [1-(% mortality in vaccinated fish/%mortality in mock vaccinated fish)] x 100.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for dip suspension.
Opaque, light yellow to brownish suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Sea bass (*Dicentrarchus labrax* L).

4.2 Indications for use, specifying the target species

For active immunisation of sea bass to reduce mortality caused by infection with *Listonella anguillarum (Vibrio anguillarum)* serotype O1 (vibriosis).

Onset and duration of immunity after vaccination according to recommended vaccination regime:
Onset of immunity: 321 degree days (2 weeks at 21 +/- 2 °C).
Duration of immunity: 1467 degree days (10 weeks at 21 +/- 2 °C).

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
Due to handling stress, vaccination may be followed by temporary reduced appetite.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Avoid skin and eye contact.

Personal protective equipment consisting of gloves and goggles should be worn when handling the veterinary medicinal product. If you get vaccine concentrate or dilution on the skin or in the eyes, rinse immediately with clean water.

In case of accidental spillage onto skin, seek medical advice immediately and show the package leaflet or the label to the physician.

Do not drink or eat while handling the vaccine.

After vaccination wash the equipment used for vaccination thoroughly.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established for use in broodstock as this veterinary medicinal product is intended for vaccination of juveniles.

4.8 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.

4.9 Amounts to be administered and administration route

Administration by dipping.

Temper the vaccine and shake the vaccine bottle prior to use.

Appearance before reconstitution: Opaque, light yellow to brownish suspension.
Dilute one litre of vaccine with 19 litres of clean sea water (1:20 dilution). Mix well.

Method of administration and posology
The following dip vaccination scheme is recommended:

First dose
Immerse fish of an average weight of 1 gram (1-2 grams) in a 1:20 vaccine to sea water dilution for 60 seconds. Discard the vaccine when a total of 20 kg of 1 gram fish have been immersed per 10 litre of the diluted vaccine.

Second dose
Immerse fish of an average weight of 5 grams (4-8 grams) in a 1:20 vaccine to sea water dilution for 60 seconds. Discard the vaccine when a total of 100 kg of 5 gram fish have been immersed per 10 litre of the diluted vaccine.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not known.

4.11 Withdrawal period

Zero degree days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for pisces, others.
ATC vet code: QI10X.

Stimulates development of active immunity in sea bass against *Listonella (Vibrio) anguillarum*

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections.
The vaccine may contain formaldehyde as a residue after inactivation.

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 42 months.
Shelf life after first opening the immediate packaging: Use immediately.
Shelf life after reconstitution according to directions: Use immediately.

6.4. Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

Polyethylene terephthalate (PET) bottle with a high-density polyethylene (HDPE) screw cap. The container is tamper evident.

Pack sizes:
500 ml bottle
1000 ml bottle

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

PHARMAQ AS
Skogmo Industriområde,
Industrivegen 50,
7863 Overhalla,
Norway

8. MARKETING AUTHORISATION NUMBER(S)

To be updated locally

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:
Date of last renewal:

10 DATE OF REVISION OF THE TEXT

To be updated locally

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.