

PACKAGE LEAFLET FOR:
ALPHA DIP Vib concentrate for dip suspension for sea bass

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

PHARMAQ AS

Skogmo Industriområde

Industrivegen 50

7863 Overhalla

Norway

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ALPHA DIP Vib concentrate for dip suspension for sea bass.

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT

Each dose contains:

Active substance:

Inactivated *Listonella anguillarum* (*Vibrio anguillarum*) serotype O1, stain AL 112 RPS¹ ≥75.

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

Opaque, light yellow to brownish suspension.

4. INDICATION

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).

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None known.

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

Sea bass (*Dicentrarchus labrax* L)

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Administration by dipping.

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.

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.

9. ADVICE ON CORRECT ADMINISTRATION

Temper the vaccine and shake the vaccine bottle prior to use. Dilute one litre of vaccine with 19 litres of clean sea water (1:20 dilution). Mix well.

Discard the vaccine when a total of 20 kg of 1 gram fish and 100 kg of 5 gram fish have been immersed per 10 litre of the diluted vaccine respectively.

10. WITHDRAWAL PERIOD

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 direct sunlight.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after “CAD/ ΛΗΞΗ/ SCAD/ VAL/ EXP:”.

Shelf life after first opening the container: Use immediately.

Shelf life after reconstitution according to directions: Use immediately.

12. SPECIAL WARNINGS

Special warnings for each target species:

Vaccinate healthy animals only.

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 used 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.

Pregnancy/Lactation/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.

Interaction with other medicinal products and other forms of interaction:

No information is available on the safety and efficacy of 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):

Not known.

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 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

DD/MM/YYYY

15. OTHER INFORMATION

Pack sizes:

500 ml bottle

1000 ml bottle

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.