ALPHA JECT micro 5, emulsion for injection for Atlantic salmon.

Authorised

- Moritella viscosa, Inactivated
- Aliivibrio salmonicida, Inactivated
- Vibrio anguillarum, serotype O2a, Inactivated
- Vibrio anguillarum, serotype O1, Inactivated
- Aeromonas salmonicida, subsp. salmonicida, Inactivated

Product identification

Medicine name:
ALPHA JECT micro 5, emulsion for injection for Atlantic salmon.

Active substance:
Moritella viscosa, Inactivated

Aliivibrio salmonicida, Inactivated

Vibrio anguillarum, serotype O2a, Inactivated

Vibrio anguillarum, serotype O1, Inactivated

Aeromonas salmonicida, subsp. salmonicida, Inactivated

Target species:
Atlantic salmon

Route of administration:
Intraperitoneal use

Product details

Active substance and strength:

Moritella viscosa, Inactivated
10.70 log2 enzyme-linked immunosorbent assay unit(s) / 0.05 millilitre(s)

Aliivibrio salmonicida, Inactivated
90.00 Relative Percentage Survival / 0.05 millilitre(s)

Vibrio anguillarum, serotype O2a, Inactivated
75.00 Relative Percentage Survival / 0.05 millilitre(s)

Vibrio anguillarum, serotype O1, Inactivated
75.00 Relative Percentage Survival / 0.05 millilitre(s)

Aeromonas salmonicida, subsp. salmonicida, Inactivated
12.60 log2 enzyme-linked immunosorbent assay unit(s) / 0.05 millilitre(s)

Pharmaceutical form:

Emulsion for injection

Withdrawal period by route of administration:

Intraperitoneal use:

- **Atlantic salmon**
  - Fish meat. 0 degree day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QI10AB03

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

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Authorisation status:

Valid

Authorised in:

Iceland

Available in:

Iceland

Package description:
10 x 500 ml injection bags made of a multilayer plastic foil with inner layer of ethylene vinyl acetate (EVA). The giving port is closed with a bromobutyl rubber stopper.
500 ml injection bags made of a multilayer plastic foil with inner layer of ethylene vinyl acetate (EVA). The giving port is closed with a bromobutyl rubber stopper.
250 ml injection bags made of a multilayer plastic foil with inner layer of ethylene vinyl acetate (EVA). The giving port is closed with a bromobutyl rubber stopper.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Full application (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:
Pharmaq AS

Marketing authorisation date:
6/10/2022

Manufacturing sites for batch release:
Pharmaq AS

Responsible authority:
Icelandic Medicines Agency

Authorisation number:
IS/2/22/008/01

Date of authorisation status change:
6/10/2022

Reference member state:
Norway

Procedure number:
NO/V/0017/001

Concerned member states:
Iceland

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Combined File of all Documents

Labelling

This document does not exist in this language (English). You can find it in another language below.

Package Leaflet

This document does not exist in this language (English). You can find it in another language below.

Summary of Product Characteristics

This document does not exist in this language (English). You can find it in another language below.