# PARTICULARS TO APPEAR ON THE OUTER PACKAGE
# CARDBOARD BOX

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLYNAV solution for injection

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 0.05 ml dose contains:
pUK-SPDV-poly2#1 DNA plasmid coding for salmon pancreas disease virus proteins: 6.0 – 9.4 µg.

## 3. PACKAGE SIZE

250 ml

## 4. TARGET SPECIES

Atlantic salmon (*Salmo salar*).

## 5. INDICATION(S)

## 6. ROUTES OF ADMINISTRATION

Intramuscular use.
Shake product gently before use.

## 7. WITHDRAWAL PERIODS

Withdrawal period: Zero degree days.

## 8. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once opened use within 10 hours.

## 9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Keep the bag in the outer carton.

## 10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

## 11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

## 12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

## 13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
D-27472 Cuxhaven
Germany

## 14. MARKETING AUTHORISATION NUMBER

Vm 52127/5003

## 15. BATCH NUMBER

Lot {number}

## 16. SPECIAL WARNING(S), IF NECESSARY

## 17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

## 18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V
To be supplied only on veterinary prescription.

# PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
## Bag (250 ml)

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLYNAV solution for injection

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 0.05 ml dose contains:

pUK-SPDV-poly2#1 DNA plasmid coding for salmon pancreas disease virus proteins: 6.0 – 9.4 µg.

## 3. TARGET SPECIES

Atlantic salmon (*Salmo salar*)

## 4. ROUTES OF ADMINISTRATION

Intramuscular use
Read the package leaflet before use.
Shake product gently before use.

## 5. WITHDRAWAL PERIODS

Withdrawal period: Zero degree days.

## 6. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once opened use within 10 hours.

## 7. SPECIAL STORAGE PRECAUTIONS

Keep the bag in the outer carton.
Store and transport refrigerated.

## 8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
D-27472 Cuxhaven
Germany

## 9. BATCH NUMBER

Lot {number}

## 10. PACKAGE SIZE

250 ml

## 11. INDICATION(S)

## 12. SPECIAL WARNING(S), IF NECESSARY

## 13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

## 14. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.
POM-V
To be supplied only on veterinary prescription.

## 15. MARKETING AUTHORISATION NUMBER

Vm 52127/5003

# PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CLYNAV solution for injection

## 2. COMPOSITION

Each 0.05 ml dose contains: pUK-SPDV-poly2#1 DNA plasmid coding for salmon pancreas disease virus proteins: 6.0– 9.4 µg.

A clear, colourless, particulate-free solution.

## 3. TARGET SPECIES

Atlantic salmon *(Salmo salar).*

## 4. INDICATIONS FOR USE

For the active immunisation of Atlantic salmon to reduce impaired daily weight gain, and reduce mortality, and cardiac, pancreatic and skeletal muscle lesions caused by pancreas disease following infection with salmonid alphavirus subtype 3 (SAV3).
Onset of immunity occurs within 399 degree days (mean water temperature in °C multiplied by number of holding days) following vaccination.
Duration of immunity: 1 year for reduction in impaired daily weight gain, and cardiac, pancreatic and skeletal muscle lesions and 9.5 months for reduction of mortality (demonstrated in a laboratory efficacy study in saltwater conditions using a cohabitation challenge model).

## 5. CONTRAINDICATIONS

None.

## 6. SPECIAL WARNING(S)

### Special warnings:

Vaccinate healthy animals only.

### Special precautions for safe use in the target species:

A minimum body weight of 25 g is recommended at vaccination.

### Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Personal protective equipment, for example, consisting of appropriate protective gloves, should be worn when handling the veterinary medicinal product.

**Fertility:**

The effect of this vaccine on reproductive performance has not been investigated. Do not use in broodstock.

**Interaction~~s~~ 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.

**Overdose:**

No effects other than those described in the section ”Adverse events” have been observed following the administration of a ten-fold overdose.

**Special restrictions for use and special conditions for use:**

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State’s competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

**Major incompatibilities:**

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with any other veterinary medicinal products.

## 7. ADVERSE EVENTS

Atlantic salmon:

| |
|---|
| Very common (> 1 animal / 10 animals treated): |
| Abnormal swimming in fish[1]<br>Fish colour change[2], Inappetance[3] |
| Common (1 to 10 animals / 100 animals treated): |
| Puncture wound[4] |

[1] For up to two days.
[2] For up to seven days.
[3] For up to nine days.
[4] Needle injuries can persist in up to 5% of fish for at least 90 days and can be seen both macroscopically and microscopically.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Intramuscular use.
Anaesthetise the fish to immobilise them, and administer 0.05 ml of the vaccine by intramuscular injection in the area immediately anterior and lateral to the dorsal fin in the epaxial muscle.

## 9. ADVICE ON CORRECT ADMINISTRATION

Shake product gently before use.
Transfer tubing kit instructions: using the spiked end, screw the transfer tubing set onto the fill port of the ethyl vinyl acetate (EVA) bag with a ¼ turn in order to secure the line in place. Connect the other end of the transfer tubing set to the vaccine injection equipment (gun).
Position the needle at 90° in the epaxial muscle, central to the dorsal fin and above the mid-line.
Based on a 25 g fish weight a standard 0.5 mm diameter 3mm depth needle is recommended to be used routinely. Consideration should be made for the weight of the fish before the final selection is made. Injection equipment should be calibrated and inspected regularly to ensure appropriate dosing of the fish.

## 10. WITHDRAWAL PERIOD(S)

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 use this veterinary medicinal product after the expiry date which is stated on the label after Exp.
Shelf life after first opening the immediate packaging: 10 hours.

## 12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

## 13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

## 14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 52127/5003

250 ml sterile, flexible, ethyl vinyl acetate (EVA) bags with a locking snap down port. A sterile and individually packaged transfer tube set is included in the final product packaging.

## 15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

October 2023

## 16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
D-27472 Cuxhaven
Germany

Tel: +44 3308221732
PV.GBR@elancoah.com

Manufacturer responsible for batch release:
Lohmann Animal Health GmbH
Heinz-Lohmann-Straβe 4
27472 Cuxhaven
Germany

## 17. OTHER INFORMATION

CLYNAV stimulates active immunity against salmonid alphavirus subtype 3 (SAV3).

CLYNAV contains a supercoiled DNA plasmid which expresses proteins of salmon alphavirus which induces a protective immune response in vaccinated Atlantic salmon.

Approved 20 October 2023