

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

CLYNAV solution for injection

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each 0.05 ml dose contains:

#### **Active substance:**

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

#### **Excipients:**

For the full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Solution for injection.

A clear, colourless, particulate-free solution.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Atlantic salmon (*Salmo salar*).

#### **4.2 Indications for use, specifying the target species**

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).

### 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

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

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

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

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

#### Special precautions for the protection of the environment:

Not applicable

#### iii) Other precautions

Not applicable

### 4.6 Adverse reactions (frequency and seriousness)

Atlantic salmon:

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

<sup>1</sup> Transient changes can be observed for up to two days.

<sup>2</sup> Transient changes can be observed for up to seven days.

<sup>3</sup> Transient changes can be observed for up to nine days.

<sup>4</sup> Needle injuries at the site of injection are common following administration of the vaccine which 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also the last section of the package leaflet for contact details.

#### **4.7 Use during pregnancy, lactation or lay**

##### Fertility:

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

#### **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 Amount(s) to be administered and administration route**

Intramuscular use.

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).

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.

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.

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

No effects other than those described in section 4.6 have been observed following the administration of a ten-fold overdose.

#### **4.11 Withdrawal period(s)**

Zero degree days.

## **5. IMMUNOLOGICAL PROPERTIES**

**Pharmacotherapeutic group:** Immunologicals for Atlantic salmon

**ATC Vet Code:** QI10AX.

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.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Potassium chloride

Potassium dihydrogen phosphate

Disodium hydrogen phosphate heptahydrate

Sodium chloride

Purified water

### **6.2 Major Incompatibilities**

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

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 14 months.

Shelf life after first opening the immediate packaging: 10 hours.

### **6.4 Special precautions for storage**

Store and transport refrigerated (2 °C – 8 °C).

### **6.5 Nature and composition of immediate packaging**

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.

### **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**

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

## **8. MARKETING AUTHORISATION NUMBER**

Vm 52127/5003

## **9. DATE OF FIRST AUTHORISATION**

26 June 2017

## **10. DATE OF REVISION OF THE TEXT**

October 2023

## **PROHIBITION OF SALE, SUPPLY AND/OR 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.

## **11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

Approved 20 October 2023

A handwritten signature in black ink, appearing to read "Hunter.", is positioned below the approval date.