

**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.

**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 OF THE MARKETING AUTHORISATION HOLDER**

MSD Animal Health UK Limited

**14. MARKETING AUTHORISATION NUMBERS**

Vm 01708/5133

**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  
Veterinary medicinal product subject to 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 OF THE MARKETING AUTHORISATION HOLDER**

MSD Animal Health UK Limited

**9. BATCH NUMBER**

Lot {number}

**10. SPECIAL WARNING(S), IF NECESSARY**

**11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Disposal: Read package leaflet

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

For animal treatment only.

POM-V

Veterinary medicinal product subject to prescription

## **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 WARNINGS**

#### **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.

**Interactions 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 <sup>1</sup><br>Fish colour change <sup>2</sup> , Inappetence <sup>3</sup> |
| Common (1 to 10 animals / 100 animals treated):                                                      |
| Puncture wound <sup>4</sup>                                                                          |

<sup>1</sup> For up to two days.

<sup>2</sup> For up to seven days.

<sup>3</sup> For up to nine days.

<sup>4</sup> 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.

E-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>.

## **8. DOSAGE FOR EACH SPECIES, ROUTES 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 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, in the area immediately anterior and lateral to the dorsal fin, along a line equidistant to the dorsal fin and the mid-line, and at the point of the muscle's maximum girth.

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 PERIODS**

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 01708/5133

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. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

### **16. CONTACT DETAILS**

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

MSD Animal Health UK Limited  
Walton Manor  
Walton  
Milton Keynes  
MK7 7AJ  
United Kingdom

Manufacturer responsible for batch release:

Merck Sharp & Dohme Animal Health S.L.  
Polígono Industrial El Montalvo I  
Calle Zeppelin 6, Parcela 38  
37008 Carbajosa de la Sagrada  
Salamanca  
Spain

## 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.  
POM-V Veterinary medicinal product subject to prescription  
For animal treatment only.

*Gavin Hall*  
Approved: 20 January 2026