ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Bag Label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

WINVIL® 3 Micro

Emulsion for Injection for Atlantic salmon.

2. STATEMENT OF ACTIVE SUBSTANCES

Active substances:

Per dose (0.05 ml) vaccine: Inactivated *Aeromonas salmonicida* subspecies *salmonicida* RPS_{end} ≥70%; inactivated *Moritella viscosa* RPS_{end} ≥83%; inactivated Infectious pancreatic necrosis virus (IPNV) Serotype A2 (RP ≥2.2 ELISA Units).

Adjuvant: Mineral oil

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

500 ml

5. TARGET SPECIES

Atlantic salmon (*Salmo salar*).

6. INDICATION(S)

For the active immunisation of Atlantic salmon (*Salmo salar*) to reduce mortality due to infection with *Aeromonas salmonicida* (furunculosis). The onset of immunity to *A. salmonicida* occurs at 446 degree days (mean water temperature °C multiplied by the number of holding days) following vaccination.

For the active immunisation of Atlantic salmon to reduce mortality due to infection with Infectious Pancreatic Necrosis Virus (IPNV).The onset of immunity to IPNV occurs at

625 degree days following vaccination.

For the active immunisation of Atlantic salmon to reduce mortality due to infection with *M. viscosa* (winter ulcer disease). The onset of immunity to *M. viscosa* occurs at 286 degree days following vaccination.

The duration of immunity to *A. salmonicida*, *M. viscosa* and IPNV is not known.

This is a Provisional Marketing Authorisation. A full set of supporting efficacy data is not available for this product. In particular, protection against specific clinical signs such as ulceration associated with *M. viscosa* has not been demonstrated.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the inner label pages before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero degree days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous – see the inner label pages before use.

10. EXPIRY DATE

EXP {dd/mm/yyyy}

Use within 10-hours of opening, remaining vaccine should be discarded at end of use.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (2°C – 8°C). Do not freeze.

Keep in the original container to protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd

Lilly House

Priestley Road

Basingstoke

Hampshire

RG24 9NL

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4080

17. MANUFACTURER'S BATCH NUMBER

Batch no. {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

WINVIL® 3 Micro emulsion for injection for Atlantic salmon

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

Marketing authorisation holder:

Elanco Europe Ltd

Lilly House

Priestley Road

Basingstoke

Hampshire

RG24 9NL

Manufacturer responsible for batch release:

Benchmark Vaccines Ltd.

4 Warner Drive

Springwood Industrial Estate

Rayne Road, Braintree

Essex CM7 2YW, UK

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

WINVIL® 3 Micro

Emulsion for Injection for Atlantic salmon

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Per dose (0.05 ml) vaccine:

Active substances: Inactivated *Aeromonas salmonicida* subspecies *salmonicida*, RPS_{end} ≥ 70 %; inactivated *Moritella viscosa*, RPS_{end} ≥ 83 %; and inactivated IPNV Serotype A2 (RP ≥ 2.2 ELISA Units).

Adjuvant: Mineral oil

Excipients: Emulsifiers, bacteriological media, tissue culture media. The vaccine may contain formaldehyde (≤ 0.5 g/litre) as a residual after inactivation.

RPS = Relative Percent Survival.

RP = Relative Potency compared to the reference vaccine

4. INDICATION(S)

For the active immunisation of Atlantic salmon (*Salmo salar*) to reduce mortality due to infection with *Aeromonas salmonicida* (furunculosis). The onset of immunity to *A. salmonicida* occurs at 446 degree days (mean water temperature °C multiplied by the number of holding days) following vaccination.

For the active immunisation of Atlantic salmon to reduce mortality due to infection with Infectious Pancreatic Necrosis Virus (IPNV). The onset of immunity to IPNV occurs at 625 degree days following vaccination.

For the active immunisation of Atlantic salmon to reduce mortality due to infection with *M. viscosa* (winter ulcer disease).

The onset of immunity to *M. viscosa* occurs at 286 degree days following vaccination.

The duration of immunity to A. salmonicida, M. viscosa and IPNV is not known.

This is a Provisional Marketing Authorisation. A full set of supporting efficacy data is not available for this product. In particular, protection against specific clinical signs such as ulceration associated with *M. viscosa* has not been demonstrated.

5. CONTRAINDICATIONS

Do not use if there are any signs of disease in the fish. Do not use in fish selected for broodstock.

6. ADVERSE REACTIONS

Fish may take up to 12 days to return to normal feeding.

Until 2,000 dd (approximately 5 months) after vaccination, fish vaccinated with this product may develop abdominal lesions that range from slight to major, and pigmentation of the viscera and fillet/abdominal wall that may range from none to moderate. Visceral granulomas may occur in < 1% of vaccinated fish.

At harvest (up to 19 months), Speilberg scores of 1, 2 and 3 are very common, scores of 4 are common.

At harvest, minor areas of melanin in the viscera and fillet/abdominal wall are very common, and moderate areas of melanin pigmentation are common.

Very common	Melanisation in the abdominal cavity
	Mild visceral adhesions (Speilberg score 1-2)
	Moderate visceral adhesions (Speilberg score 3)
Common	Serious visceral adhesions ((Speilberg score 4)

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))

- common (more than 1 but less than 10 animals in 100 animals treated)

- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)

- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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

Atlantic salmon (*Salmo salar*)

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

For intraperitoneal injection only. Each 500 ml of vaccine is sufficient to vaccinate 10,000 fish.

To use, fish are anaesthetised until immobilised and administered 0.05 ml by intraperitoneal injection, on the midline, one pelvic fin length ahead of the pelvic girdle. The needle should be at right angles to the skin surface. It is recommended that fish be at least 47.4 g in size for injection administration. A minimum water temperature of 2°C for vaccination is recommended.

9. ADVICE ON CORRECT ADMINISTRATION

Shake product well before use.

Do not mix with any other veterinary medicinal product.

Administration of the vaccine must be performed using an injection system that prevents back-flush of the vaccine in to the vaccine tube/container.

The vaccine should be at 15-20°C before use. Oil based vaccines are best injected at 15 - 20°C to facilitate vaccine delivery and to avoid damage and stress to the fish.

A separation of the emulsion can occur over time, leading to a triphasic appearance. The upper layer appears as clear oily layer. The middle layer represents the majority of the finished product (creamy emulsion) and appears as a pale yellow. The bottom layer is brown coloured.

Thorough mixing of the bag before beginning administration and at intervals during vaccination will return the product to a homogeneous appearance. This minor separation has no effect on the safety or efficacy of the product.

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 freeze.

Store in the original container in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

Shelf life after first opening the container: 10 hours

Remaining vaccine should be discarded at end of use.

12. SPECIAL WARNINGS

Special warnings for each target species:

It is recommended that all fish within the stock population are vaccinated in order to reduce infection spread.

Fish should be starved for a period of 24 hours prior to vaccination and preferably at least

24 hours post vaccination. Feed should gradually be re-introduced to fish post vaccination over several days until full appetite is resumed.

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 consisting of gloves and guarded needles should be worn when handling the veterinary medicinal product.

To the user:

This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This veterinary medicinal product contains mineral oil. Even if only a small amount is injected, accidental injection in man can lead to very severe swelling that may result in an ischaemic necrosis and even loss of the affected finger. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.

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

July 2020

Approved 30 July 2020