SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

WINVIL® 3 Micro
Emulsion for Injection for Atlantic salmon

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose (0.05 ml) vaccine

Active substances:

Inactivated *Aeromonas salmonicida* subspecies *salmonicida*	RPS ≥ 70 %
Inactivated *Moritella viscosa*	RPS_{end} ≥ 83%
Infectious pancreatic necrosis virus (IPNV) Serotype A_2	RP ≥ 2.2

RPS = Relative Percent Survival
RP = Relative Potency compared to a reference vaccine

Adjuvant:

Mineral oil	43.62 %

Excipients:

Formaldehyde (residual inactivant)	< 0.025 % (w/v)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.

Pale yellow emulsion.

A separation of the emulsion can occur over time, leading to a triphasic appearance where the upper layer appears as a clear oily phase, the middle layer as a pale yellow creamy emulsion and the bottom layer appears as a dark brown aqueous phase.

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 (*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.

4.3 Contraindications

Do not use if there are any signs of disease in the fish. See section 4.7.

4.4 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.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

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 small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. 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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

Do not use in fish selected for 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 Amounts to be administered and administration route

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.

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.

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

No adverse reactions other than those described in section 4.6 are observed.

4.11 Withdrawal period(s)

Zero degree days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated vaccines for fish
ATC vet code: QI10AL0

The vaccine stimulates the development of active immunity against *Aeromonas salmonicida* subspecies *salmonicida* (furunculosis), *Moritella viscosa* (winter ulcers) and IPNV (infectious pancreatic necrosis virus) in Atlantic salmon.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mineral oil
Polyoxyethylene sorbitan monooleate

Sorbitan sesquioleate
Phosphate buffered saline
Residual formaldehyde

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 12 months
Shelf life after first opening the immediate packaging: Use within 10 hours of opening, remaining vaccine should be discarded at end of use.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Keep in the original container to protect from light.

6.5 Nature and composition of immediate packaging

The product is supplied in a single tube intravenous bag with a plastic screw cap closure and a plastic clamp off device together with a fluid transfer tubing.
Pack size: 500 ml (10,000 doses)

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 Europe Ltd
Lilly House
Priestley Road
Basingstoke
Hampshire
RG24 9NL

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4080

9. DATE OF FIRST AUTHORISATION

10 July 2014

10. DATE OF REVISION OF THE TEXT

30 July 2020

Approved 30 July 2020