SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Birnagen Forte As Emulsion for Injection for Atlantic Salmon

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances
1 dose (0.1 ml) contains:

Inactivated *Aeromonas salmonicida* (As27)	RPS_{60}* ≥80%
Inactivated Infectious Pancreatic Necrosis Virus (IPNV)	RP** ≥ 1.22

* RPS_{60}: Relative Percent Survival
** RP: relative potency compared to a reference vaccine.

Adjuvant

Mineral oil (Drakeol 6VR)	43.62%

Excipients

Formaldehyde (residual inactivant)	< 0.5% (w/v)

See section 6.1 for a complete list of excipients

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target Species

Atlantic salmon (*Salmo salar*) weighing at least 35 g.

4.2 Indications for Use

For the active immunisation of Atlantic salmon (*Salmo salar*) to prevent mortality due to infection with *Aeromonas salmonicida* (furunculosis).
The onset of immunity to *A. salmonicida* is no later than 430 degree days following vaccination.
The duration of immunity to *A. salmonicida* has been demonstrated up to 2000 degree days following vaccination.

For the active immunisation of Atlantic salmon to reduce clinical signs and mortality due to infection with Infectious Pancreatic Necrosis Virus (IPNV).
In laboratory trials, the onset of immunity to IPNV has been shown to be no later than 771 degree days following vaccination.

In field trials, the vaccine has been shown to reduce mortality compared to controls in the face of IPNV challenge after transfer to sea 600 degree days after vaccination.

4.3 Contraindications

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

4.4 Special warnings

Vaccinate only healthy fish. 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 at least 24 hours and preferably 48 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.

The user should note that physical and environmental conditions pre-vaccination, at the time of and post-vaccination influence the side effects seen in fish from site to site. These conditions include fish size, health and condition, water temperature, correct vaccination practice including handling and stress pre and post vaccination.

4.5 Special precautions for use

i. Special precautions for use in animals

Not applicable.

ii. Special precautions to be taken by the person administering the medicinal product to animals

Ensure that the method of restraint, handling and administration, e.g. by the use of guarded needles, minimizes the risk of accidental injection/self injection.

<u>To the user:</u>

This 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 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 5 days to return to feeding. Appetite and weight gain may be reduced for 21 days after vaccination.

Vaccination may cause some degree of visceral adhesions within the peritoneal cavity, a characteristic of vaccines that incorporate an oil adjuvant. Adhesions may be moderate or even severe if vaccine is not properly delivered into the body cavity. Peak occurrence of side effects in correctly vaccinated fish are typically observed 3 to 6 months post sea transfer. Melanisation of viscera and muscle may also occur.

At 6 months post sea transfer, the incidence of mild adhesions (not noticeable to the layman) was very common (>93% of vaccinated fish) and of moderate adhesions was common (<7% of vaccinated fish).

4.7 Use during pregnancy, lactation or lay

Do not use in fish selected for broodstock.

4.8 Interactions with other 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.
Shake product well before use.

The vaccine should be warmed to 15-20°C before use. For injection use, each litre of vaccine is sufficient to vaccinate 10,000 fish. To use, fish are anaesthetised until immobilised and administered 0.1 ml intraperitoneally, on the midline, one pelvic fin length ahead of the pelvic girdle. It is recommended that fish be at least 35 g in size for

injection administration. A minimum water temperature of 2°C for vaccination is recommended.

It is essential to mix the vaccine prior to and during treatment to ensure correct consistency of the product for administration/treatment. Oil based vaccines are best injected at 15-20ºC to ensure ease of vaccination for vaccinator and to avoid damage to the fish.

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

No adverse reactions other than those described in section 4.6 are observed following administration of a two-fold overdose.

4.11 Withdrawal period(s)

Zero degree days.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against *Aeromonas salmonicida* and Infectious Pancreatic Necrosis Virus (IPNV).

ATC vet code: QI10AA01/AB01

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Mineral oil (Drakeol 6VR)
Sorbitan sesquioleate
Polyoxyethylene sorbitan monooleate
Formaldehyde (residual inactivant)
Phosphate buffered saline

6.2 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: 1 year.
Shelf-life after first opening the immediate packaging: Use within 10 hours. Any partly used containers of vaccine should be discarded at the end of each day's operations.

6.4 Special precautions for storage

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

6.5 Nature and contents of the immediate packaging

1000 ml EVA (plastic) intravenous bag with a plastic screw cap (ABS terluran/high density polyethylene) closure and a plastic clamp off device.

6.6 Special precautions for the disposal of unused medicinal product or waste materials derived from the use of such products

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORIZATION HOLDER

Novartis Animal Vaccines Ltd
Frimley Business Park
Frimley
Camberley
Surrey
GU16 7SR

8. MARKETING AUTHORISATION NUMBER

Vm 18343/4015

9. DATE OF FIRST AUTHORISATION

Date: 13 August 2010

10. DATE OF REVISION OF THE TEXT

Date: June 2013

APPROVED T. NASH **20/06/13**