SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norvax Compact PD emulsion for injection for Atlantic Salmon

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of 0.1 ml contains:

Active substance:
Inactivated salmon pancreas disease virus (SPDV) strain F93-125, ≥ 70% RPP*
* RPP: relative percentage protection in a laboratory potency test in Atlantic Salmon

Adjuvant:
Montanide ISA 763A VG 63 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
Homogenous, white to slightly pink emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Atlantic Salmon (*Salmo salar* L)

4.2 Indications for use, specifying the target species

For the active immunisation of Atlantic salmon to reduce heart lesions, mortality and weight loss caused by pancreas disease.

Onset of immunity: 500 degree days.
Duration of immunity: at least 12 months for reduction of heart lesions and 18 months for reduction of mortality and weight loss.

4.3 Contraindications

None.

4.4 Special warnings for each target species

The vaccine should not be used in diseased or unhealthy fish, fish receiving medical treatment or fish during smoltification.
Vaccine efficacy at temperatures below 10 °C has not been documented.

4.5 Special precautions for use

Special precautions for use in animals
Vaccination at higher water temperatures (exceeding 17 °C) can increase local reactions.
Vaccination of fish below the recommended weight may increase local reactions.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Personal protective equipment consisting of e.g. needle protector should be used when handling the product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

To the user:
This veterinary medicinal product contains mineral oil (Montanide). 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 (Montanide). 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)

After vaccination with Norvax Compact PD very slight lesions may be observed in the abdominal cavity. At nine weeks post vaccination a Speilberg score of 1 is very commonly observed (average Speilberg score is 0.61). At harvest these lesions have resolved.
Spinal deformities of the so-called “cross-stitch vertebrae” type, have been rarely reported after the use of Norvax Compact PD. These deformities are believed to have multifactorial causes and are possibly linked to a component of the PD vaccine.

For adverse reaction when used in association with Norvax Minova 6, see section 4.8.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)

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

4.7 Use during pregnancy, lactation or lay

Do not use in broodstock. The possible effects of primary vaccination on spawning have not been investigated.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data* are available which demonstrate that this vaccine can be administered at least 240 degree days or at least 3 weeks before the administration of Norvax Minova 6 (where this vaccine is authorised).

*Efficacy data are available for 5 of the 6 components of Norvax Minova 6; for the *Moritella viscosa* component no data are available.

When fish are vaccinated with Norvax Compact PD followed by Norvax Minova 6 melanisation and an increase in the frequency and severity of abdominal lesions ranging from very slight to major lesions may be observed throughout the production cycle compared to vaccination with Norvax Compact PD alone. At harvest Speilberg scores 1 and 2 are very common and scores 3 and 4 are common (average Speilberg score is 1.7) when both vaccines are used in association.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. 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

For intraperitoneal use.

Dose: a single dose of 0.1 ml.
Administration route: intraperitoneal injection along the central line, 1 pelvic fin length in front of the pelvic fin base.
Shake the bottle well before use.

Vaccination is recommended for fish above 35 grams.

Food should be withheld 1–2 days prior to vaccination. The fish should be anaesthetised before vaccination. The length and the diameter of the needle used should be adapted to the size of the fish. Ensure the recommended dose is deposited into the abdominal cavity before the needle is withdrawn.

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

After administration of a double dose Speilberg scores 1, 2 and 3 are very commonlyobserved (average Speilberg score is 2.05).

4.11 Withdrawal period(s)

Zero degree days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Pisces; Atlantic salmon; inactivated viral vaccines.
ATCvet code: QI10AA01.

Stimulates active immunity against pancreas disease in Atlantic salmon.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Montanide ISA 763A VG
Water for injections

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: 18 months.
Shelf life after first opening the immediate packaging: 4 hours.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C). Do not freeze.

6.5 Nature and composition of immediate packaging

Bottles of polyethylene terephthalate (PET) closed with a rubber stopper and aluminium cap.
Pack sizes: 250 ml (2,500 doses) or 500 ml (5,000 doses).
Not all pack sizes may be marketed.

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

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

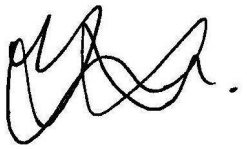
Vm 01708/4551

9. DATE OF FIRST AUTHORISATION

10 August 2011

10. DATE OF REVISION OF THE TEXT

September 2022



Approved: 08 September 2022