LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norvax Compact PD emulsion for injection for Atlantic Salmon

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per dose of 0.1 ml: inactivated salmon pancreas disease virus, ≥70% RPP

Montanide ISA 763A VG 63 mg

3. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

250 ml (2,500 doses)
500 ml (5,000 doses)

5. TARGET SPECIES

Atlantic salmon

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intraperitoneal use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: zero degree days.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental self-injection is dangerous.
Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached use within 4 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.

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

Disposal: read package leaflet.

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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4551

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Norvax Compact PD 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 and manufacturer responsible for batch release:
MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norvax Compact PD emulsion for injection for Atlantic Salmon

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

One dose of 0.1 ml contains:

Active substances
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.

Homogenous, white to slightly pink emulsion.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

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 12.

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).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Atlantic salmon (*Salmo salar* L)

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

Dose: 0.1 ml per fish.

Route of administration: The vaccine should be administered by intraperitoneal injection. The correct site of injection is along the central line, 1 fin length in front of the pelvic fin base.

9. ADVICE ON CORRECT ADMINISTRATION

Vaccination is recommended for fish above 35 grams.
Shake the bottle well before use.

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 (0.1 ml) is deposited into the abdominal cavity before the needle is withdrawn (for injection site see section 8).
Use of standard vaccination equipment and a “cradle with neck cord” is recommended.

10. WITHDRAWAL PERIOD

Zero degree days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.
Shelf life after first opening the container: 4 hours.

12. SPECIAL WARNING(S)

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 evaluated.

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.

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

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 products 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.

Overdose (symptoms, emergency procedures, antidotes):
After administration of a double dose of Norvax Compact PD Speilberg scores 1, 2 and 3 are very commonly observed (average Speilberg score is 2.05).

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

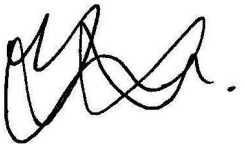
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2022

15. OTHER INFORMATION

Pack sizes: 250 ml (2,500 doses) or 500 ml (5,000 doses).

Not all pack sizes may be marketed.



Approved: 08 September 2022