LABELLING AND PACKAGE LEAFLET

PACKAGE LEAFLET/LABEL:[1]
AquaVac FNM^{PLUS} emulsion for injection for fish
Aquavac FNM emulsion for injection for fish (ES, FR)

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

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release: [2]
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire, MK7 7AJ
United Kingdom

Merck Sharp & Dohme Animal Health S.L.
Poligono Industrial El Montalvo I
C/Zeppelin 6, Parcela 38,
37008 Carbajosa de La Sagrada (Salamanca)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac FNM^{PLUS}, emulsion for injection for fish

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

Each dose (0.1 ml) of vaccine contains:

Actives substances:
Inactivated cells of *Aeromonas salmonicida,* strain MT004 and strain MT423 inducing RPS_{60}[1] ≥ 80% after vaccination.

[2]RPS_{60} = relative percentage of survival in vaccinates at 60% control mortality.
Adjuvant:

[1]This text will form the label for the product. There is no separate leaflet for this product. The text numbering is taken from the template for the package leaflet and under 15. Other Information is given the additional information required by the label template
[2] The printed package leaflet will state the name and address of the manufacturer responsible for the release of the concerned batch only.

Montanide ISA 711: 0.07 ml

Excipients:
Residual formaldehyde ≤ 0.05% (w/v)
A homogenous emulsion with a creamy-white oily appearance.

4. INDICATION(S)

For the reduction of mortality due to furunculosis disease caused by *Aeromonas salmonicida.*
Immunity develops progressively after vaccination, the rate being dependent upon water temperature.

Onset of immunity: at 12°C, a minimum of 28 days should be allowed between vaccination and anticipated exposure to infection. For general guidance, a period equivalent to 400 degree-days should be allowed for development of optimum immunity.
Duration of immunity: has been demonstrated under field conditions for at least 5 months after vaccination.

5. CONTRAINDICATIONS

Do not vaccinate fish with AquaVac FNM^{PLUS} more than once.

6. ADVERSE REACTIONS

Some inflammation in the body cavity in the vicinity of the injection site is very commonly observed and is part of the immune response. Side effects in the form of visceral adhesions occur very commonly in fish, but are minor in extent (Speilberg score not more than 3). Some melanisation may very commonly occur. Slightly increased levels of fin rot are uncommonly observed following vaccination against furunculosis. External signs such as scale loss and haemorrhage at the point of injection and more serious internal reactions are rarely present if injection technique is good.

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

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

The minimum size of fish for vaccination is 25 g.
Administer by intraperitoneal injection at a dose of 0.1 ml per fish. Inject fish, previously anaesthetised with an approved anaesthetic, centrally into the abdomen, 1 – 2 fin lengths in front of the base of the pelvic fins. The needle should point forward at an angle of about 45° and in a 25g fish, penetrate to a depth of approximately 2 - 3mm.

9. ADVICE ON CORRECT ADMINISTRATION

Shake the bottle well before use.

Administer using a multi-dose injection applicator with a 6 mm, 22 gauge needle, incorporating a mechanism to prevent flush-back. This applies equally to semi-automatic (hand held) and automatic systems.

Careful injection technique is important to minimise adverse reactions.

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.
Protect from light.

Shelf-life after first opening the container: 5 hours.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals only.
Do not vaccinate fish at the water temperatures below 1 ºC.

Special precautions for use in animals
Do not vaccinate fish during the smoltification process.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

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 of 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.

Fertility:
Do not use in fish intended as brood stock.

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 case by case basis.

Overdose:
No adverse observations have been noted as a result of administration of a double dose other than those mentioned in section “Adverse Reactions” of this leaflet.

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

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

Ask your veterinary surgeon or pharmacist 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

October 2020

15. OTHER INFORMATION

For animal treatment only.

Package size: 500 ml
Pharmaceutical form: Emulsion for injection
Marketing authorisation number: {As allocated by the Member State}

Batch {number}
EXP {month/year}