

1. SUMMARY OF PRODUCT CHARACTERISTICS**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

AquaVac® IridoV

2. QUALITATIVE COMPOSITIONActive substance(s)

Fish iridovirus

Adjuvant:

Oil adjuvant

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. CLINICAL PARTICULARS**4.1 Target species**

Fish.

4.2 Indications for use

For active immunization of susceptible fish species (see also 4.4) to reduce mortality due to Iridovirus.

Onset of immunity has been demonstrated 10 days after vaccination at a water temperature of 27°C (270 degrees days). Duration of immunity has been demonstrated for at least 15 weeks after a single vaccination.

4.3 Contraindications

None known.

4.4 Special warnings

The vaccine has been tested for safety and efficacy in Tilapia (*Oreochromis* sp.) and Asian sea bass (*Lates calcarifer*) as representative species. The vaccine may be used in other fish species. However, if so, its use should be undertaken with care and it is advisable to test the vaccine on a small number of fish prior to mass vaccination.

4.5 Special precautions for use**Special precautions for use in animals**

Fish should be healthy and free of disease at the time of vaccination. Sick or weak fish may not develop adequate immunity.

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 insert or label to the physician.

1. SUMMARY OF PRODUCT CHARACTERISTICS

To the user:

This product contains 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 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

A small proportion of treated animals may show very slight local reactions.

4.7 Use in broodstock animals

No adverse reaction expected.

4.8 Interaction with other medicinal products and other forms of interaction

The vaccine can be used in combination with other compatible oil based injection vaccines from the AquaVac vaccine range, such as AquaVac® Strep Sa, AquaVac® Strep Sa1 and AquaVac® TenaSi.

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

Food should be withheld for a period of 1 day prior to vaccination.

Avoid stress in the period prior to and after vaccination.

Sterile injection equipment should be used.

For injection, fish should be anaesthetised.

Shake the vaccine well before use.

Inject 0.05 ml intraperitoneally halfway between the base and tip of the pelvic fins in fish of minimum 5 gram.

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

No other symptoms expected than those mentioned in 4.6.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against Iridovirus.

1. SUMMARY OF PRODUCT CHARACTERISTICS

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

None known.

6.2 Shelf life

Shelf-life of the product as packaged for sale: 3 year

Opened bottles should be used promptly (within 5 hours) and should not be stored.

6.3 Special precautions for storage

Store at 2 - 8°C. Protect from light. Do not freeze.

6.4 Nature and composition of immediate packaging

Plastic bottles closed with a rubber stopper and sealed with an aluminium cap.

Package size: 1 000 doses, 2 000 doses, 5 000 doses, or 10 000 doses. Not all pack sizes may be marketed.

6.5 Special precautions for the disposal of unused 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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International BV

ANNEX A. LABELLING**PARTICULARS TO APPEAR ON THE OUTER PACKAGE OR ON THE IMMEDIATE PACKAGE**

- 1. NAME OF THE VETERINARY MEDICINAL PRODUCT**
AquaVac® IridoV
- 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES**
The vaccine contains inactivated Iridovirus with oil adjuvant.
- 3. INDICATIONS FOR USE**
Vaccine against fish iridovirus
- 4. PACKAGE SIZE**
1 000 doses, 2 000 doses, 5 000 doses, or 10 000 doses
- 5. METHOD AND ROUTE(S) OF ADMINISTRATION**
Inject 0.05 ml intraperitoneally halfway between the base and tip of the pelvic fins in fish of minimum 5 gram.
For details, see package insert.
- 6. EXPIRY DATE**
EXP:
- 7. SPECIAL STORAGE CONDITIONS**
Shake well before use. Store dark at 2-8°C. Do not freeze.
- 8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**
For animal treatment only
- 9. THE WORDS "KEEP OUT OF REACH AND SIGHT OF CHILDREN"**
Keep out of reach and sight of children
- 10. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**
Product of Intervet International B.V.
Boxmeer – the Netherlands
- 11. MANUFACTURER'S BATCH NUMBER**
LOT:

ANNEX B. PACKAGE LEAFLET**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

AquaVac® IridoV

2. STATEMENT OF THE ACTIVE SUBSTANCE(S)

The vaccine contains inactivated Iridovirus with oil adjuvant.

**3. PRODUCT OF INTERVET INTERNATIONAL
BOXMEER – THE NETHERLANDS****4. INDICATION(S)**

Aid in protection against Iridovirus infections in susceptible fish species (see also section 12 below).

5. CONTRA-INDICATIONS

None known.

6. ADVERSE REACTIONS

A small proportion of treated animals may show very slight local reactions.

7. TARGET SPECIES

Fish.

8. DOSAGE FOR EACH SPECIES

Each animal should receive one dose of vaccine

9. ADVICE ON CORRECT ADMINISTRATION

- Food should be withheld for a period of 1 day prior to vaccination.
- Avoid stress in the period prior to and after vaccination.
- Sterile injection equipment should be used.
- For injection, fish should be anaesthetised.
- Shake the vaccine well before use.
- Inject 0.05 ml intraperitoneally halfway between the base and tip of the pelvic fins in fish of minimum 5 gram.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Store at 2 - 8°C. Protect from light. Do not freeze.

12. SPECIAL WARNINGS, IF NECESSARY**Special precautions for use in animals**

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13. OTHER INFORMATION

For animal treatment only.