

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE*

Bottle (label)

** The label and leaflet are presented in a fold-out format. The label text of this section will appear twice in the packaging material ie. in the outermost face of the fold-out and the inner face in the closest contact of the bottle.*

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AquaVac Vibrio Immersion and Injection concentrate for dip suspension and suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 1 ml of vaccine (concentrate) contains:

Active substance:

Vibrio anguillarum, serotype O1, strain 78-SKID, inactivated: RPS₆₀(*) > 75%

*Vibrio ordalii*¹, strain MSC 275, inactivated: RPS₆₀(*) > 75%

¹ *Vibrio ordalii* is a subset of *Vibrio anguillarum* O2

(*) RPS₆₀: relative percentage survival in vaccinees, at time of 60% of mortality in controls, after vaccination by injection and subsequent challenge.

3. PACKAGE SIZE

1000 ml

4. TARGET SPECIES

Rainbow Trout (*Oncorhynchus mykiss*)

5. INDICATIONS**6. ROUTES OF ADMINISTRATION**

Immersion or intraperitoneal use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero degree days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use immediately by immersion, use within 5 hours by intraperitoneal use.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.

Do not freeze.

Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name}

14. MARKETING AUTHORIZATION NUMBERS

{to be completed nationally}

15. BATCH NUMBER

Lot {number}