

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

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

Pharmaq Limited

Unit 15

Sandleheath Industrial Estate

Fordingbridge

Hants SP6 1PA

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aquatet 100% w/w Premix for Medicated Feeding Stuff

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

Oxytertracycline hydrochloride as the B.P. substance

4. PHARMACEUTICAL FORM

A fine yellow powder comprising

5. PACKAGE SIZE

6. INDICATION(S)

Use for the treatment and control of *Aeromonas* spp, *Yersinia* spp, *Vibrio* spp and *Myxobacteria* spp. in Atlantic Salmon and Rainbow Trout.

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

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

For administration in fish food.

Dosage: 75 mg/kg bodyweight of fish daily for initially 4 days. After the initial treatment, mortalities should be assessed and a further 4 day treatment course should be administered if necessary.

11. ADVICE ON CORRECT ADMINISTRATION

The product is for administration only through the feed by mixing with manufactured feed prior to feeding. Feeding rates will vary according to the water temperature and it may therefore be more convenient to medicate on the basis of a fixed rate, e.g. 1% of bodyweight, with the extra daily feed requirement being met by unmedicated food.

The following inclusion rates will provide the recommended dose.

Daily feed rate (% bodyweight)	Aquatet powder inclusion rate		
	Per 5kg food	Per 25kg food	Per 1 tonne feed
½	75g	375g	15kg
1	37.5g	187.5g	7.5kg
2	18.75g	93.75g	3.75kg

Method of mixing: -

Weigh out appropriate amounts of fish pellets and product and mix well together in a dry state. As an aid to the adhesion of the product to the fish pellets, a small quantity of a tepid gelatin solution of edible oil is then added to the food while mixing. Sufficient quantity should be mixed into the medicated food until it is slightly dampened.

12. WITHDRAWAL PERIOD

Animals must not be slaughtered for human consumption during treatment,

Fish may be slaughtered for human consumption from 720° days after the last treatment.

13. SPECIAL STORAGE PRECAUTIONS

Store in a dry place. Re-close part used containers. Do not store above 25°C. Protect from light. Medicated diet should be used for the treatment period only.

14. SPECIAL WARNING(S)

When mixing oxytetracycline, rubber gloves should be worn to avoid the possibility of skin reactions and a respirator which at least complies with European Standard EN149, FFP2 to avoid inhalation of any dust particles.

15. EXPIRY DATE

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

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

18. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

[Distribution category]

POM-V

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

Keep out of the sight and reach of children

20. MARKETING AUTHORISATION NUMBER(S)

Vm 11003/4002

21. MANUFACTURER’S BATCH NUMBER

22. OTHER INFORMATION

Pack size: 1 kg or 2.5 kg

Approved: 10/01/2018

