

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

Vetremox Fish 100% w/w Powder for Top-Dressing Use

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

Amoxicillin as Amoxycillin trihydrate

4. PHARMACEUTICAL FORM

White to cream coloured granular powder comprising

5. PACKAGE SIZE

6. INDICATION(S)

Amoxycillin is a broad-spectrum semi-synthetic penicillin which has bactericidal activity against Gram-negative and Gram-positive bacteria including *Aeromonas salmonicida*. The major indication is for the treatment of Furunculosis in Atlantic salmon, caused by *Aeromonas salmonicida*

7. CONTRAINDICATIONS

8. ADVERSE REACTIONS

9. TARGET SPECIES

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

For incorporation with already manufactured feeding stuffs.

Vetremox is administered at the rate of 80mg/kg bodyweight. A ten day course of treatment is recommended.

11. ADVICE ON CORRECT ADMINISTRATION

Vetremox Powder is for administration only through feed by mixing with manufactured feed prior to feeding. Feeding rates will vary according to water temperature and it may therefore more convenient to medicate on a 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.

Produce Inclusion Rate			
Daily feed rate % bodyweight	Per 5kg	Per 25kg of feed	Per tonne of feed
0.5	80g	400g	16.0kg
1	40g	200g	8.0kg
2	20g	100g	4.0kg

As an aid to the adhesion of the product, edible oil or tepid gelatine solution is added to the feed while mixing until the feeds slightly dampened. The medicated feed should then be allowed to dry before feeding to the fish.

During the mixing of Vetremox Powder with fish pellets, small quantities of powder may settle out. This should not be administered with the fish food.

12. WITHDRAWAL PERIOD

Fish must not be slaughtered for human consumption during treatment. Atlantic salmon may be slaughtered for human consumption only after 500 degree days from the last treatment.

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Store in a dry place.

Store in tightly closed original container

Medicated feed: use at once after preparation: Do not store.

14. SPECIAL WARNING(S)

Operators should avoid the possibility of skin contact or inhalation of this product. Suitable protective clothing, including gloves and a respirator should be worn. The respirator should comply with BS 2091 (Type A respirator) or BS 6106 (Type 1 respirator). Wash thoroughly after removal of protective clothing.

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross reactions to cephalosporins and vice versa. Allergic reaction to these substances may occasionally be serious.

1. Do not handle this product if you know you are sensitised, or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure taking all recommended precautions.
3. If you develop symptoms following exposure, such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty in breathing are more serious symptoms and require urgent medical attention.

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

For animal treatment only

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)

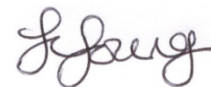
Vm 11003/4005

21. MANUFACTURER’S BATCH NUMBER

22. OTHER INFORMATION

Reviewed: January 2018

Approved: 10/01/2018

A handwritten signature in black ink, appearing to read "J. Berg".