SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetremox Fish 100% w/w Powder for top-dressing use

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Amoxicillin trihydrate 100% w/w

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for top-dressing use

A fine white to cream crystalline powder

4. CLINICAL PARTICULARS

4.1 Target species

Atlantic salmon

4.2 Indications for use, specifying the target species

Furunculosis in Atlantic salmon, caused by Aeromonas salmonicida

4.3 Contraindications

In common with all other penicillins, Amoxycillin should not be used orally or parenterally in rabbits, guinea pigs, hamsters, gerbils or other very small herbivores.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i. Special precautions for use in animals

None.

ii. Special precautions for the person administering the veterinary medicinal product to animals

Avoid skin contact. Whilst handling the product wear coveralls, protective goggles and chemically resistant impermeable gloves at all times.

Avoid inhalation of dust. Wear either a disposable half-mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143.

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.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Product knowledge suggests resistance to antimicrobials in aquatic situations appears readily. It is recommended that resistance patterns in relevant pathogenic bacteria should be monitored.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

Not to be administered with other antibacterials.

4.9 Amount(s) to be administered and administration route

Dose Regime

The product is administered at the rate of 80mg/kg bodyweight per day. A ten day course is recommended.

Method of Administration

The product 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.

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

None.

4.11 Withdrawal period(s)

Atlantic salmon may be slaughtered for human consumption only after 500 degree days from the last treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Antibacterials for systemic use (amoxicillin)

ATC Vet Code: QJ01CA04

5.1 Pharmacodynamic properties

A broad-spectrum semi-synthetic penicillin which has bactericidal activity against Gram-negative and Gram-positive bacteria.

5.2 Pharmacokinetic properties

Amoxicillin is acid stable, well absorbed following oral administration in the presence of feed and is excreted via the kidneys.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months

6.4 Special precautions for storage

i) Do not store above 25°C.
ii) Store in a dry place.
iii) Store in tightly closed original container
iv) Medicated feed: use at once after preparation: Do not store.

6.5 Nature and composition of immediate packaging

400g, 1kg, 2kg, 3.2kg, 4kg, 5kg and 10kg
White polypropylene tubs with white polypropylene lids and low density polyethylene liner..

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

Pharmaq Limited
Unit 15
Sandleheath Industrial Estate
Fordingbridge
Hants SP6 1PA

8. MARKETING AUTHORISATION NUMBER(S)

Vm 11003/4005

9. DATE OF FIRST AUTHORISATION

12th April 1999

10. DATE OF REVISION OF THE TEXT

August 2010