SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Aquatet 100% w/w Premix for Medicated Feeding Stuff

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredient:

Qualitative composition	Quantitative composition
Oxytetracycline hydrochloride	100% w/w

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Premix for Medicated Feeding Stuff
A fine, bright, yellow, odourless, crystalline powder

4. CLINICAL PARTICULARS

4.1 Target species

Salmon and rainbow trout

4.2 Indications for use, specifying the target species

Treatment and control of furunculosis due to Aeromonas salmonicida and columnaris disease in Atlantic salmon, and furunculosis and enteric redmouth disease in Rainbow trout.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.
Do not administer together with Growth Promoters or other antibiotics

4.4 Special warnings for each target species

For fish treatment only.

4.5 Special precautions for use

i. Special precautions for use in animals

Medicated feed should be used for the treatment period only.

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

If you know you are hypersensitive (allergic) to oxytetracycline, do not handle the product.
When handling the product, inhalation of the dust must be avoided by wearing a disposable half-mask respirator conforming to European Standard EN 149 (FFP2) or a non-disposable respirator to European Standard EN 140 with a filter to EN 143.
Avoid contact with skin and eyes. Gloves should be worn whilst handling this product. If contact with skin or eyes occurs, wash area immediately with copious amounts of fresh water. If irritation persists, seek medical attention.
Hands and exposed skin should be washed thoroughly after use.

iii. Other precautions

It is essential to obtain consent from the local regional office of the Environment Agency or SEPA before using Aquatet medicated feed.

4.6 Adverse reactions (frequency and seriousness)

No adverse effects are observed when the product is administered at recommended dose rate.

4.7 Use during pregnancy, lactation or lay

This product may be used on brood stock.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer together with Growth Promoters or other antibiotics.

4.9 Amount(s) to be administered and administration route

For oral administration.

The product is given by oral administration at a rate of 75mg/kg bodyweight of fish, daily for initially 4 days. After the initial treatment, mortalities should be assessed and a further 4 days treatment course should be administered if necessary.

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.

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

Oxytetracycline has a wide safety margin. Furthermore, the product administered onto food in this manner cannot be expected to lead to overdose.

4.11 Withdrawal period(s)

Animals must not be slaughtered for human consumption during treatment,

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use (oxytetracycline)

ATC Vet Code: QJ01AA06

5.1 Pharmacodynamic properties

Oxytetracycline is a broad-spectrum antibiotic. It also inhibits mycoplasmas chlamydiae, rickettsiae and some protozoa. When dosed orally, it is readily absorbed and achieves effective concentrations in various tissues.

5.2 Pharmacokinetic properties

Oxytetracycline is a broad spectrum bacteriostatic agent and is used as a drug of first choice for many bacterial diseases of fish. Absorption, distribution, metabolism and elimination of Oxytetracycline varies between species of fish and is temperature and salinity dependent. Its mechanism of action is via inhibition of protein synthesis of susceptible bacteria.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Aquatet is incompatible with Calcium products and certain Growth Promoters and bactericidal antibacterials.

6.3 Shelf life

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

6.4 Special precautions for storage

Store in a dry place. Store in a tightly closed original container. Do not store above 25°C. Protect from light.
Due to the hydroscopic nature of the product, any open part packs of the veterinary medicinal product should be discarded and not resealed for use at a later date.
Medicated feed should be prepared as required and not stored.

6.5 Nature and composition of immediate packaging

White, food grade polyethylene tub or bucket, with a white polypropylene tamper evident lid (push fit) with low density polyethylene liner.

Sizes: 1kg tub, 2.5kg bucket.

OR, Polyethylene liner, inside a fibreboard drum

Sizes: 25kg

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 11003/4002

9. DATE OF FIRST AUTHORISATION

Date: 14th March 1994

10. DATE OF REVISION OF THE TEXT

Date: May 2011