

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Aquatet 100% w/w Oral Powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Oxytetracycline hydrochloride 100 % w/w

3 PHARMACEUTICAL FORM

Oral powder.

4 CLINICAL PARTICULARS

4.1 Target Species

Salmon.

4.2 Indications for use, specifying the target species

Treatment and control of furunculosis due to *Aeromonas salmonicida* in Atlantic salmon.

4.3 Contraindications

Fish must not be slaughtered for human consumption during treatment.

4.4 Special warnings for each target species

Medicated feed should be used for the treatment period only.

4.5 Special precautions for use

Special precautions for use in animals:

None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Avoid inhaling dust, wear rubber gloves and a dust mask which at least complies with European Standard EN149, FFP2 to avoid inhalation of any dust particles.

4.6 Adverse reactions (frequency and seriousness)

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

4.7 Use during pregnancy, lactation or lay

This product may be used on broodstock.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer together with Growth Promoters or other antibiotics.

4.9 Amounts to be administered and administration route

For oral administration.

Administer orally via the food at a dose rate of 75mg/kg bodyweight daily, initially for 4 days. After the initial treatment mortalities should be assessed and a further 4 days course of treatment should be administered if necessary. This product is administered 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 un-medicated food.

The following inclusion rate will provide the recommended dose:

Aquatet Daily feeding rate % bodyweight	(Oxytetracycline) Per 25 kg	content per tonne
½	375.0 g	15.0 kg
1	187.5 g	7.5 kg
2	93.75 g	3.75 kg

Method of mixing:

Weigh out appropriate amounts of fish pellets and Aquatet powder and mix well together in a dry state. As an aid to the adhesion of the Aquatet powder to the fish pellets, a small quantity of a tepid gelatin solution or 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, Aquatet administered onto the food in this manner cannot be expected to lead to overdose.

4.11 Withdrawal Period(s)

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Therapeutic group; Antibiotic.

ATC Code; QJ01AA06

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.

Medicated feed should be prepared as required and not stored.

6.4 Special precautions for storage

Do not store above 25°C. Store in tightly-closed original container.

Store in a dry place. Protect from light. Securely re-close part-used containers after use.

6.5 Nature and composition of immediate packaging

White, food grade polypropylene tub and bucket with low density polyethylene liner and white, food grade, push-fit, tamper evident lid.

Sizes: 1 kg tub, 2.5 kg bucket.

Fibreboard drum with double low density polyethylene liner inside an aluminium compound foil bag.

Size: 25 kg.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Pharmaq Ltd.,
Unit 15,
Sandleheath,
Fordingbridge,
SP6 1PA,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10885/1/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

22nd March 2006

10 DATE OF REVISION OF THE TEXT

July 2014