Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Maracycline Powder 100 % w/w Premix for Medicated Feed

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance

Oxytetracycline hydrochloride 100% w/w

3 PHARMACEUTICAL FORM

Pre-mix for medicated feed.
A yellow crystalline powder.

4 CLINICAL PARTICULARS

4.1 Target Species

Atlantic Salmon

4.2 Indications for use, specifying the target species

For the treatment and control of furunculosis due to *Aeromonas salmonicida* in Atlantic Salmon.

4.3 Contraindications

Do not use in cases of known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Use of this product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria. Whenever possible the product should only be used on the basis of susceptibility testing.

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

Pregnant women should not handle this product.
When mixing this product, protective goggles, impervious gloves and a filtering face-piece respirator (CEN standard FFP1) should be worn, to avoid direct contact with the skin and inhalation of the product.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

It is not recommended to mix this product in feedingstuff containing other antibiotics or with growth promoters.

4.9 Amounts to be administered and administration route

The recommended daily dose rate is 75 mg oxytetracycline hydrochloride per kg of fish bodyweight. A 10 day course of treatment is recommended. The product should be incorporated in pelleted feed or mixed with feed just prior to feeding. The following inclusion rate for different feeding rates (which vary according to water temperature and size of fish) will provide the recommended dose:

Daily feed rate	**Rate of inclusion**	
% bodyweight	per 25 kg feed	per tonne feed
0.5	375.00 g	15.00 kg
1	187.50 g	7.50 kg
2	93.75 g	3.75 kg

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

Do not exceed the stated dose. Occasional allergic reactions do occur but these are rare.

4.11 Withdrawal Period(s)

Fish must not be slaughtered for human consumption during treatment.

Atlantic salmon may be slaughtered for human consumption only after 400 degree days from the last treatment (eg. 50 days at 8^0C or 40 days at 10^0C).

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC Vet Code: QJ01AA06

Pharmacotherapeutic Group: Antibacterials for systemic use, oxytetracycline.

There is a clear effect of water type (sea or fresh) and a temperature effect on the kinetics of oxytetracycline in fish. In the case of the results obtained by O'Grady et al (1986) the lower dose rate (80 $mg.kg^{-1}$) was of the same order as that recommended for Maracycline Powder (75$mg.kg^{-1}$) and the serum levels were in the order of 1.4 $\mu g.ml^{-1}$ for freshwater. Higher dose rates (200-240 $mg.kg^{-1}$) resulted in higher serum levels.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Not applicable.

6.2 Incompatibilities

It is not recommended to mix this product in feeding stuff containing other antibiotics or with growth promoters.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 1 year
Shelf-life after first opening the immediate packaging: 3 months

6.4 Special precautions for storage

Do not store above 25°C.
Store in a dry place.
Keep container tightly closed.

6.5 Nature and composition of immediate packaging

2 kg & 20 kg HDPE sealed bags, placed in HDPP buckets and fibre board drums, respectively.

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

Univet Ireland Limited
Tullyvin
Cootehill
County Cavan

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10990/031/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

2nd October 2007

10 DATE OF REVISION OF THE TEXT

13th March 2009