Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Maracycline 500 mg/g Premix for Medicated Feeding Stuff

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of powder contains:

Active Substance

Oxytetracycline (as Oxytetracycline hydrochloride) 500mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Premix for medicated feeding stuff
A pale yellow, homogenous, free flowing mix

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 the product should be based on susceptibility testing of the bacteria isolated from the fish. 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 based on susceptibility testing

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after use.
When mixing this product, protective goggles and a dust mask to BS 2091 or BS 6061 should be worn, to avoid direct contact with the skin and inhalation of the product. Pregnant women should not handle this product.

4.6 Adverse reactions (frequency and seriousness)

Occasional allergic reactions occur but these are rare.

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 feeding stuff containing other antibiotics or with growth promoters.

4.9 Amounts to be administered and administration route

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

Daily Feeding Rate	Rate of Inclusion	
% bodyweight	per 25 kg of feed	per tonne of feed
0.5	750.0 g	30.0 kg
1	375.0 g	15.0 kg
2	187.5 g	7.5 kg

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

Do not exceed the stated dose.

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 for the last treatment (e.g. 50 days at 8^{o}C or 40 days at 10^{o}C).

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antibacterials for systemic use, tetracyclines
ATCvet Code: QJ01AA06

5.2 Pharmacokinetic properties

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 10% w/w Powder* (75 mg.kg $^{-1}$) and the serum levels were in the order of 1.4 µg.ml $^{-1}$ for seawater and 2.0 µg. 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

Lactose
Colloidal Anhydrous Silica

6.2 Incompatibilities

None known

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 1 year.

Shelf-life after incorporation into meal or pelleted feed: 3 months

6.4 Special precautions for storage

Store below 25°C.
Store in a dry place.
Keep the container tightly closed

6.5 Nature and composition of immediate packaging

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

Not all pack sizes may be marketed

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Univet Ltd.,
Tullyvin,
Cootehill,
Co. Cavan,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10990/029/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

24th July 2009

10 DATE OF REVISION OF THE TEXT

18th May 2010