## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Maracycline powder 1000 mg/g premix for medicated feeding stuff for Atlantic salmon.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

**Active substance:**
Oxytetracycline hydrochloride 1000 mg

A yellow crystalline powder.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Atlantic salmon.

### 3.2 Indications for use for each target species

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

### 3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance.

### 3.4 Special warnings

None.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:

Use of this veterinary medicinal 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 veterinary medicinal 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:

Personal protective equipment consisting of protective goggles, impervious gloves and a filtering face-piece respirator (CEN standard FFPl) should be worn when handling the veterinary medicinal product to avoid direct contact with the skin and inhalation of the veterinary medicinal product.
Pregnant women should not handle this veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation

holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
None known.

### 3.8 Interaction with other medicinal products and other forms of interaction

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

### 3.9 Administration routes and dosage

In-feed use.
The recommended daily dose rate is 75 mg oxytetracycline hydrochloride per kg of fish bodyweight. A 10 day course of treatment is recommended. The veterinary medicinal 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 of feed | per tonne of feed |
| 0.5 | 375.0 g | 15.0 kg |
| 1 | 187.5 g | 7.5 kg |
| 2 | 93.75 g | 3.75 kg |

### 3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Do not exceed the stated dose.

### 3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

### 3.12 Withdrawal periods

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 (e.g. 50 days at 8 °C or 40 days at 10 °C).

## 4. PHARMACOLOGICAL INFORMATION

**ATCvet code :**

QJO1AA06

### 4.2 Pharmacokinetics

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) was of the same order as that recommended for the veterinary medicinal product (75mg/kg) and the serum levels were in the order of 1.4 flg/mt for freshwater. Higher dose rates (200-240 mg/kg) resulted in higher serum levels.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

None known.

### 5.2 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.

### 5.3 Special precautions for storage

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

### 5.4 Nature and composition of immediate packaging

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

Not all pack sizes may be marketed.

### 5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Univet Limited

## 7. MARKETING AUTHORISATION NUMBER(S)

VPA10990/031/001

## 8. DATE OF FIRST AUTHORISATION

03/10/1997

## 9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

17/08/2026

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).