

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tricaine Pharmaq 1000 mg/g Powder for Solution for Fish Treatment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Tricaine methanesulfonate 1000 mg/g

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for solution for fish treatment.
White to off-white powder.

4. CLINICAL PARTICULARS

4.1 Target species

- 1) Ornamental fish, or their development stages, and
- 2) Breeding and juvenile stages of fish.

4.2 Indications for use, specifying the target species

For use in an immersion bath for sedation, immobilisation and anaesthesia of fish for: vaccination, transportation, weighing, tagging, clipping, stripping of breed stock, blood-sampling and surgical procedures.

4.3 Contraindications

Do not use in the following tropical fish species:

Apistogramma (Mikrogeophagus) ramirez, *Balantiocheilos melanopterus*, *Etroplus suratensis*, *Melanotaenia maccullochi*, *Monodactylus argenteus*, *Phenacogrammus interruptus* and *Scatophagus argus*

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Do not exceed the dose recommended for each category of fish.

Brood stock anaesthetised for stripping should be immersed in unmedicated water immediately before collection of eggs or milt to avoid significant direct contact of either with the product.

As solutions of the veterinary medicinal product are slightly acidic, the use of phosphate or imidazol buffer has been proposed to reduce stress.

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

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to Tricaine mesilate (Tricaine methanesulfonate) should avoid contact with the veterinary medicinal product.

Personal protective equipment consisting of impermeable rubber gloves should be worn when handling the veterinary medicinal product.

Do not create dust when handling the powder or preparing the anaesthetic solution. In case of accidental inhalation of dust, move to fresh air and if breathing is affected, seek medical advice immediately and show the doctor the product label. In situations where dust is created when handling the powder, wear a disposable half mask respirator conforming to European Standard EN 149 or a non-disposable respirator to European Standard EN 140 with a filter to EN 143.

Avoid contact with skin and eyes. In case of accidental contact, immediately wash the affected area with plenty of clean running water. If irritation persists, seek medical advice.

Do not eat, drink or smoke whilst handling this product.
Wash hands after use.

Other precautions

In order to protect the environment, used solution **must either be filtered using activated charcoal filters** prior to dilution in the effluent to be discharged from the farm **or it must be transferred to a holding tank filled with water with subsequent controlled release** for dilution in the effluent to be discharged from the farm, see section 6.6.

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

Tricaine methanesulfonate has been used successfully at lower concentrations in conjunction with several other anaesthetics. No adverse interaction with other pharmaceuticals has been established.

4.9 Amounts to be administered and administration route

An aqueous solution of the product is used in an immersion bath for sedation, immobilisation and anaesthesia of fish, both ornamental and those intended for human consumption.

A number of factors influence the efficacy and safety of the product, including concentration of the drug in water, duration of exposure, previous exposures to the drug, temperature, oxygen content and density of biomass. Because of these variable factors it is strongly recommended that a test of the selected drug concentration and exposure time is conducted with a small group of representative fish before large numbers are medicated. This is especially important when water temperature is at the upper or lower ends of the normal temperature ranges for the species being treated. The product should be dissolved in water of the same composition and characteristics as that to which the fish are accustomed. As the product has good aqueous solubility, it may be added directly to the container. Effects on the fish should be monitored as the product is gradually introduced.

Before anaesthesia, or prolonged sedation, fish should be fasted for 12 to 24 hours. During treatment they should be stocked at a density not exceeding 80g/litre. To minimise damage and loss when medicated for long periods for transport etc. the level of sedation should allow fish to maintain their equilibrium and swimming position. Aeration should be provided unless sedation, or anaesthesia, is of short duration. In anaesthesia loss of reflexes takes place in one to fifteen minutes after immersion depending upon concentration employed. Narcotised fish should be removed from medicated water and returned to their normal environment as soon as possible, when recovery will take between one and thirty minutes.

The following examples of dose rates and exposure times are based on laboratory and field experience:

| | | Concentration mg/litre of water | Immersion time (mins) |
|-------------------------------|--------|---------------------------------------|-----------------------------|
| Trout species (7-17°C) | | | |
| Sedation | | 10-30 | Up to 480 |
| Anaesthesia | Light | 30-80 | Up to 30 |
| | Deeper | 80-180 | Up to 10 |
| Salmon species | | | |
| Sedation | | 7-30 | Up to 240 |
| Anaesthesia | Light | 30-80 | Up to 10 |
| | Deeper | 80-100 | Up to 5 |
| Bass species | | | |
| Sedation | | 8-30 | Up to 480 |
| Anaesthesia | Light | 30-70 | Up to 20 |

| | Deeper | 70-100 | Up to 4 |
|----------------------------------|--------|--------|------------|
| Carp species | | | |
| Sedation | | 20-30 | Up to 1440 |
| Anaesthesia | | 30-200 | Up to 8 |
| Fresh water tropical fish | | | |
| Sedation | | 30-50 | Up to 1440 |

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

Remove fish immediately to aerated water of the same composition and temperature that is free from anaesthetic. Overdose or prolonged exposure to the product may cause respiratory failure and death.

4.11 Withdrawal period(s)

- Fish must not be slaughtered for human consumption during treatment.
- Fish can only be harvested for human consumption 70 degree days after the last treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anaesthetics, general, other general anaesthetics.
ATCvet code: QN01AX93

5.1 Pharmacodynamic properties

Tricaine methanesulfonate has properties slightly different from, but similar to, both ester and amide anaesthetics, acting as a general anaesthetic or narcotic. It is more water-soluble than Benzocaine, lending it to fish application. Fish are normally immersed in solutions and both absorption and excretion occur through the gill epithelium.

The drug causes reduced blood flow through the gills and reduced oxygen consumption. The rate at which narcosis is induced depends upon the concentration of the product in water and also upon the water temperature. At higher temperatures onset or narcosis is more rapid; however the safety margin is less. Immersion of fish in unmedicated water reverses narcotic effects.

5.2 Pharmacokinetic particulars

Tricaine methanesulfonate is soluble in lipids, which probably accounts for its rapid diffusion across gills in both directions, with rapid anaesthesia and rapid recovery. The drug is distributed throughout the body.

Excretion occurs mainly across the gill epithelium. Non-polar ethyl meta-aminobenzoate and its N-acetyl derivative are both excreted across the gills, whereas the polar meta-aminobenzoic acid and its N-acetyl derivative are excreted via the kidneys. All species tested appear to produce an acetylated derivative, to the extent normally of less than 20% of the original anaesthetic. The hydrolysis to produce the free acid also varies with species, so kidney excretion will vary between

species. However, the effectiveness varies less between species owing to the free movement of the drug across the gills.

The concentration in salmonid muscle, whilst the fish is under anaesthetic, ranges from 9.4 to 72.0 mg/kg. The half life of the anaesthetic in muscle on withdrawal is approximately 70 minutes. Thus 24 hours gives 20 half lives. The highest concentrations found in salmonid muscle after 24 hours have been 2.6 to 3.2 mg/kg (the oral LD in a 30kg dog is 30,000 x 4mg of the anaesthetic).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after dilution or reconstitution according to directions: 24 hours.

6.4. Special precautions for storage

Store in the original container.

Keep the container tightly closed in order to protect from moisture.

Store in a dry place.

Protect from direct sunlight.

This veterinary medicinal product does not require any special temperature storage conditions.

6.5 Nature and composition of immediate packaging

High Density Polyethylene (HDPE) tamper resistant tubs closed with an integral, tamper evident, low density polyethylene cap (snap on) or polypropylene screw cap containing either 25g, 100g, 250g or 1000g.

Not all pack sizes may be marketed.

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

Used solution **must either be filtered using activated charcoal filters** prior to dilution in the effluent to be discharged from the farm **or it must be transferred to a holding tank filled with water with subsequent controlled release** for dilution in the effluent to be discharged from the farm.

Filtration

Filtration of used solution through an activated charcoal filter will ensure that the concentration of spent tricaine methanesulfonate in discharge water does not exceed 1 µg/L. Spent carbon filters should be disposed of in accordance with local requirements

Holding tank

Transfer of used solution to a holding tank filled with water and controlled release for dilution in the effluent will ensure that the concentration of spent tricaine methanesulfonate in discharge water does not exceed 1 µg/L when releasing the solution from the holding tank at flow rates calculated in the table below (1 000L and 50 000L holding tanks). Discharge flows for different sized holding tanks can be calculated as shown in the 50 000L column.

| Farm flow rate (L/min) | Discharge flow (L/h) from holding tank | |
|------------------------|--|-----------------------|
| | 1000 L holding tank | 50 000 L holding tank |
| 10 000-14 999 | 15 | (50*15) 750 |
| 15 000-19 999 | 22 | (50*22) 1100 |
| 20 000-24 999 | 30 | (50*30) 1500 |
| 25 000-29 999 | 37 | (50*37) 1850 |
| 30 000-35 000 | 45 | (50*45) 2250 |

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

Pharmaq Ltd
Unit 15, Sandleheath Industrial Estate
Fordingbridge
Hampshire
SP6 1PA

8. MARKETING AUTHORISATION NUMBER

Vm 11003/4014

9. DATE OF FIRST AUTHORISATION

07 February 2013

10 DATE OF REVISION OF THE TEXT

April 2018

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke at the end.

Approved 01 May 2018