1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tricaine Pharmaq 1000 mg/g powder for solution for fish treatment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:
Tricaine methanesulfonate 1000 mg/g

Excipients: None

White crystalline powder.

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each 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.

3.3 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 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:

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.

Special precautions for the protection of the environment:

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 5.5.

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

Not applicable.

3.8 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.

3.9 Administration routes and dosage

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.

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.

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, salinity and hardness of water, size of fish (smaller are more susceptible) 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.

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 30 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 (7-17ºC)			
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

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

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.

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.
- Fish can only be harvested for human consumption 70 degree days after the last treatment.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QN01AX93

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after dissolution according to directions: 24 hours

5.3 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 solution from direct sunlight.
This veterinary medicinal product does not require any special temperature storage conditions.

5.4 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 in a cardboard box.

Pack sizes:
25 g, 100 g, 250 g and 1000 g

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.

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 (1 000 liter and 50 000 liter holding tanks). Discharge flows for different sized holding tanks can be calculated as shown in the 50 000 liter 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

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

PHARMAQ AS

7. MARKETING AUTHORISATION NUMBER(S)

VPA10804/006/001

8. DATE OF FIRST AUTHORISATION

08/03/2013

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

22/05/2026

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).