PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Tricaine methanesulphonate 1000 mg/g

3. PHARMACEUTICAL FORM

Powder for solution for fish treatment.

4. PACKAGE SIZE

25 g
100 g
250 g
1000 g

5. TARGET SPECIES

Fish.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For use in solution as an anaesthetic bath.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: 70 degree days

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP: month/year

11. SPECIAL STORAGE CONDITIONS

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.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet for further information on filtration and dilution to reduce environmental exposure.
Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

To be supplied only on veterinary prescription.

POM-VPS

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 11003/4014

17. MANUFACTURER'S BATCH NUMBER

Lot

PACKAGE LEAFLET:
Tricaine Pharmaq 1000mg/g Powder for Solution for Fish Treatment

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

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

Manufacturer responsible for batch release:

PHARMAQ AS
7863 Overhalla
Norway

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT(S)

Tricaine methanesulfonate 1000 mg/g.
No other excipients or active substances.

White powder for dissolution in water and subsequent topical application.

4. INDICATION(S)

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 for: vaccination, transportation, weighing, tagging, clipping, stripping of breed stock, blood sampling and surgical procedures.

5. 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.

6. ADVERSE REACTIONS

None known.

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Fish.
Specifically, ornamental fish, or their development stages, and breeding and juvenile stages of fish.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

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

		Concentration mg/litre of water	**Immersion time (minutes)**
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

9. ADVICE ON CORRECT ADMINISTRATION

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. 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 30 minutes.

10. WITHDRAWAL PERIOD

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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

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

12. SPECIAL WARNING(S)

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 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 a phosphate or imidazol buffer has been proposed to reduce stress.

Overdose (symptoms, emergency procedures, antidotes):

In case of overdose, 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.

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

- transferred to a holding tank with subsequent controlled release for dilution in the effluent to be discharged from the farm. See section 13 for further advice.

Incompatibilities:

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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).

Using the table below, select the appropriate farm flow rate interval and use the pre-calculated discharge flow for release from a 1 000L holding tank to calculate the flow rate from the holding tank size applied. Adjust the flow rate from the holding tank into farm effluent accordingly. As an example the flow rates for a 50 000 L holding tank is also shown.

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.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package sizes: 25g, 100g, 250g and 1000g.

Not all pack sizes may be marketed.
For animal treatment only. To be supplied only on veterinary prescription.

Approved: 21 November 2018