1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MS222 PHARMAQ 100% w/w Powder for Solution for Fish Treatment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Qualitative composition	Quantitative composition
Tricaine Methane Sulphonate	100%

Excipients:

For a 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

These include transportation, weighing, tagging, clipping, stripping of breed stock, blood-sampling and surgical procedures.

4.3 Contraindications

The product should not be used in the following tropical fish species:
Apistogramma ramirezi, Balantocheilus melanopterus, Etroplus surrantensis, Melanotaenia macculochi, Monodactylus argenteus, Phenacogrammus interrupts and Scalopagus argus.

4.4 Special warnings for each target species

The product should not be used in the following tropical fish species:

Apistogramma ramirezi, Balantocheilus melanopterus, Etroplus surrantensis, Melanotaenia macculochi, Monodactylus argenteus, Phenacogrammus interruptus and Scalopagus argus.

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 MS222 PHARMAQ anaesthetic solutions are slightly acidic, the use of a 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

- If you know you are hypersensitive (allergic) to anaesthetics such as Tricaine mesilate (Tricaine methane sulphonate), do not handle the 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.
- Wear impermeable rubber gloves when handling the product or solution.
- 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

- None.

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 Methane Sulphonate 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, temperature, oxygen 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. 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 recover will take between one and thirty minutes.

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

		MS222 PHARMAQ 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

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 from human consumption 70 degree days after the last treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anaesthetics, anaesthetics general, ethers, ATCvet code: QN01A

5.1 Pharmacodynamic properties

Tricaine methane sulphonate 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.

It 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. 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

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 the kidney excretion varies with 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). The withdrawal period set is 70 degree days.

5.3 Environmental properties

None known.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

No major incompatibilities have been demonstrated for any species in the range of species for which the product is recommended.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after dilution or reconstitution according to directions: 12 hours.

6.4. Special precautions for storage

Do not store above 25ºC.
Protect from direct sunlight.
Store in the original container.
Store in a dry place.
Keep the container tightly closed in order to protect from moisture.
Re-seal open packets immediately after use to exclude moisture.
Protect solution from direct sunlight.

6.5 Nature and composition of immediate packaging

High Density Polyethylene (HDPE) tamper resistant tubs closed with and integral, tamper evident, low density polyethylene cap (snap on) 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 product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Pharmaq Limited
Unit 15
Sandleheath Industrial Estate
Fordingbridge
Hampshire SP6 1PA
United Kingdom

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10 DATE OF REVISION OF THE TEXT