

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

MS 222 (Tricaine methane sulphonate) 100 %w/w Powder for solution for fish treatment.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

### Active substance:

Tricaine methane sulphonate      100% w/w

## 3 PHARMACEUTICAL FORM

Powder for solution for fish treatment.  
A white powder.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

- i) Ornamental fish, or their developmental stages, and
- ii) Breeding and juvenile stages of fish for human consumption. Depending on the concentration of the solution and/or the duration of exposure, MS222 acts as a sedative or anaesthetic in fish.

### 4.2 Indications for use, specifying the target species

For sedation, immobilisation and anaesthesia of fish. Indications for use include transportation, weighing, tagging, clipping, stripping of brood stock, blood-sampling, vaccination and surgical procedures of fin fish.

### 4.3 Contraindications

Do not use in the following tropical fish species:

*Apistogramma ramirezi*, *Balantiocheilus melanopterus*, *Etroplus surrantensis*, *Melanotaenia maccullochi*, *Monodactylus argenteus*, *Phenacogrammus interruptus* and *Scalopagus argus*.

### 4.4 Special warnings for each target species

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

## 4.5 Special precautions for use

### Special precautions for use in animals:

The stability of dilute solutions of MS222 is limited and should be protected from direct sunlight and only be used on the day of preparation; after which a fresh solution should be prepared for each use.

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 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 fish:

People who are allergic to ester type anaesthetics such as Tricaine mesilate (Tricaine methane sulphonate) should not handle this 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, wear a disposable half mask respiratory conforming to European Standard EN149 when handling the powder. Wear latex or rubber gloves when handling the product or solution. Avoid contact with skin and eyes. In case of accidental contact, immediately wash the effected area with plenty of clean running water. If irritation persists, seek medical advice. Do not eat, drink or smoke whilst handling the product.

## 4.6 Adverse reactions (frequency and seriousness)

None observed.

## 4.7 Use during pregnancy, lactation or lay

Not applicable.

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

MS222 has been used successfully at lower concentrations in conjunction with several other anaesthetics. No adverse interactions with other pharmaceuticals have 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 content, salinity and hardness of the drug in 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. 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.

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

		<b>MS222 Concentration mg/litre of water</b>	<b>Immersion time(minutes)</b>
Trout species (7-17°C)		10-30	Up to 480
Sedation:	Light	30-80	Up to 30
Anaesthesia:	Deeper	80-180	Up to 10
Salmon species		7-30	Up to 240
Sedation:	Light	30-80	Up to 10
Anaesthesia:	Deeper	80-100	Up to 5
Bass species		8-30	Up to 480
Sedation:	Light	30-70	Up to 20
Anaesthesia:	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

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.

## 4.11 Withdrawal Period(s)

Fish must not be slaughtered for human consumption during the treatment. Fish may be slaughtered for human consumption only after 70 degree days from the last treatment.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anaesthetics, anaesthetics general  
ATCvet code: QN01AX93

### 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.

### 5.2 Pharmacokinetic properties

Tricaine methane sulphonate 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 of narcosis is more rapid; however the safety margin is less. Immersion of fish in unmedicated water reserves narcotic effects. 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 tissue concentration of tricaine methane sulphonate declines progressively with time following withdrawal; whereas the concentration of the acetylated derivative increases as a proportion of the total drug in tissues up to nine hours following withdrawal and then declines.

## 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 according to directions: 24 hours.

### 6.4 Special precautions for storage

Do not store above 25°C.  
Store in a dry place away from sunlight.  
Store in a tightly closed original container.

## **6.5 Nature and composition of immediate packaging**

High Density Polythylene (HDPE) tamper proof containers containing 25g, 100g or 1000g of flammable powder.

Not all pack sizes may be marketed

## **6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials**

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

Users are recommended to set aside a suitable container for the degradation of TMS that should be left undisturbed and exposed to sunlight for a minimum period of 30 days, following which the residue may be disposed of in soil away from water courses.

## **7 MARKETING AUTHORISATION HOLDER**

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

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10797/001/001

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

25th May 2012

## **10 DATE OF REVISION OF THE TEXT**

May 2012