ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE>

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syncaine 1000 mg/g Powder for solution for fish treatment.
Tricaine methanesulfonate.

2. STATEMENT OF ACTIVE SUBSTANCES

100% Tricaine methanesulfonate (1000 mg/g)

3. PHARMACEUTICAL FORM

White to off-white powder for solution for fish treatment

4. PACKAGE SIZE

1000g, 250g, 100g, 25g,

5. TARGET SPECIES

Ornamental fish and fish intended for human consumption, and their breeding or development stages.

6. 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.

For use in solution as an anesthetic bath.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD (S)

Withdrawal period: 70 degree days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP: MM/YYYY

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

11. SPECIAL STORAGE CONDITIONS

Keep out of the sight and reach of
children. Do not store above 25°C
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. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Unused medicinal product, drug residues and packaging should be discarded in accordance with local requirements.

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.>

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

Keep out of the sight and reach of children (as in section 11).

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elara Pharmaservices Limited
Iron Farm, 7 Grimes Gate
Diseworth
Derby
DE74 2QD
United Kingdom

16. MARKETING AUTHORISATION NUMBER

POM-VPS: Vm 41203/4000

17. MANUFACTURER'S BATCH NUMBER

Lot: XXXXX

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Syncaine 1000 mg/g Powder for Solution for Fish Treatment
Tricaine methanesulfonate

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

Marketing authorization holder:
Elara Pharmaservices Limited
Iron Farm, 7 Grimes Gate
Diseworth
Derby
DE74 2QD
United Kingdom

Manufacturing authorization holder responsible for batch release:
Elara Pharmaservices Europe Ltd.
Iron Farm
7 Grimes Gate
Diseworth
Derby DE74 2QD
Quality@elarapharmaservices.com

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Syncaine 1000 mg/g Powder for Solution for Fish Treatment
Tricaine methanesulfonate

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

The veterinary medicinal product is a white to off-white powder for solution for fish treatment and subsequent topical application, containing 1000 mg/g Tricaine methanesulfonate and no other excipients or active substances.

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

The product should not be used in the following tropical fish species: *Apistogramma (Mikrogeophagus) ramirez, Balantiocheilos melanopterus, Etroplus suratensis, Melanotaenia maccullochi, Monodactylus argenteus, Phenacogrammus interruptus* and *Scatophagus argus.*

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

Ornamental fish and fish intended for human consumption, and their breeding or development stages.

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

Dosage:
An aqueous solution of the product is used in an immersion bath for sedation, immobilization 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 (mins)**
Trout species (7-17ºC)			
Sedation		10-30	Up to 480
Anaesthesia	Light Deeper	30-80 80-180	Up to 30 Up to 10
Salmon species			
Sedation		7-30	Up to 240
Anaesthesia	Light Deeper	30-80 80-100	Up to 10 Up to 5
Bass species			
Sedation		8-30	Up to 480
Anaesthesia	Light Deeper	30-70 70-100	Up to 20 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 previous exposures to the drug, concentration of the drug in water, duration of exposure, 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 minimize 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(S)

Fish: 70 degree days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of
children. Do not store above 25°C
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

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:

Tricaine methanesulfonate (tricaine mesilate) is irritating if it comes into contact with eyes, respiratory system and uncovered skin.
People with known hypersensitivity to tricaine methanesulfonate should avoid contact with the veterinary medicinal product.
Personal protective equipment consisting of impermeable rubber gloves should be worn when handling unmixed preparations and when using mixed preparations.
Avoid contact with skin and eyes. In case of accidental contact, immediately wash with plenty of clean running water. If irritation persists, seek medical advice.
Use in a well-ventilated area and do not create dust when handling the powder or preparing the anaesthetic solution. 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 conforming to European Standard EN 140 with a filter to EN 143. 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 case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not eat, drink or smoke whilst handling this product.
Wash hands after use.

Special precautions for use in animals:

- Brood stock anesthetized 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 imidazole buffer has been proposed to reduce stress

Overdose:

- In case of overdose, remove fish immediately to aerated water of the same composition and temperature that is free from anesthetic. Overdose or prolonged exposure to the product may cause respiratory failure and death.
- Do not exceed the dose recommended for each category of fish.

Other precautions:

In order to protect the environment, used solution must be 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 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 transferred to a holding tank filled with water with subsequent controlled release for dilution in the effluent to be discharged from the farm.
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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<15. OTHER INFORMATION>

POM-VPS: Vm 41203/4000
25g, 100g, 250g, 1000g pack sizes.

Not all pack sizes may be marketed.

United Kingdom
Elara Pharmaservices Europe Ltd.
Iron Farm, 7 Grimes Gate
Diseworth Derby DE74 2QD
Quality@elarapharmaservices.com

Approved 10 November 2022