

[Version 9.1,11/2024]

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FINQUEL vet. 1000 mg/g powder for immersion, solution, anesthetic for Atlantic salmon, rainbow trout and experimentally for cod

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances: Tricaine mesylate 100%

White or almost white powder.

3. CLINICAL INFORMATION

3.1 Target species

Atlantic salmon (*Salmo salar* L.), rainbow trout (*Oncorhynchus mykiss*), cod (*Gadus morhua*).

3.2 Indications for use for each target species

For sedation and anaesthesia of Atlantic salmon, rainbow trout and experimentally cod in relation to vaccination and handling (for example sorting, weighing, stripping etc.).

3.3 Contraindications

None.

3.4 Special warnings

Safety of the veterinary medicinal product at temperatures $< 7\text{ }^{\circ}\text{C}$ and $> 17\text{ }^{\circ}\text{C}$ is not documented.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The veterinary medicinal product is irritating if it comes in contact with eyes, respiratory organs and uncovered skin.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. If in contact with eyes, rinse with water and contact physician. Personal protective equipment consisting of gloves and dust mask should be worn when handling the unmixed veterinary medicinal product. Use gloves when handling the mixed product and avoid spillage in eyes and mouth.

In rare cases hypersensitive people and/or people with occupational overexposure may develop methemoglobinemia after contact with the veterinary medicinal product.

Special precautions for the protection of the environment:

If concentrated emissions to water occurs the water for the recipient must be sufficiently diluted.

3.6 Adverse events

Atlantic salmon, rainbow trout and experimentally for cod:

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 its local representative 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

Pregnancy and lactation:

Laboratory studies in minnow (*Pimephales promelas*) and rainbow trout (*O. mykiss*) have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

When used in fresh water the veterinary medicinal product has best effect if the anaesthetic solution is buffered with sodium bicarbonate to ensure neutral pH in the anaesthetic solution. A stock solution of Finquel is made by weighing the powder needed and water is then added. The same method is used to make a stock solution of sodium bicarbonate. The stock solutions must be made separately and must not be mixed. The same amount of stock solution of both Finquel and sodium bicarbonate must be added to the anaesthetic tub. This will give a clear solution. When used in sea water buffering is not needed. The stock solution must be used the same day. The mixed anaesthetic solution must be changed several times during the day.

The anaesthetic solution must be oxygenated (7 mg/l).

It is recommended to test the mixed anaesthetic solution on a smaller group of the representative fish.

The dosage is temperature-dependent.

Dosage for salmon and rainbow trout:

Indication	Dosage mg/l	Maximum residence time in the anaesthetic solution	Recovery time after transfer to fresh water
Sedation	15 – 30	6 hours	-
Anaesthesia	50 – 60	30 minutes	2-20 hours
Fast anaesthesia	80 – 135	4 – 12 minutes	3 – 19 minutes

Dosage for cod:

Indication	Dosage mg/l	Maximum residence time in the anaesthetic solution	Recovery time after transfer to fresh water
Anaesthesia	50	5 minutes	Appr. 4 minutes

For cod: if inadequate effect the dose can be elevated to 60 mg/l.

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

If overdose occurs the fish must be transferred to fresh water and assuring perfusion of the gills until normal respiration is restored.

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

Meat and offal: 25 degree days.

If cod is slaughtered within 21 days, the liver must be discarded.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QN01AX93

4.2 Pharmacodynamics

The mode of action is via non-receptor depolarisation of cell membranes with influence on the Na⁺ and K⁺ channels. This results in a blocking of the impulse transfer in the nervous system.

4.3 Pharmacokinetics

Tricaine mesylate is rapidly absorbed via the gills of the fish. The active part of tricaine mesylate is the non-polar tricaine base. The proportion of tricaine base is higher at neutral pH than at low pH. Tricaine mesylate is rapidly metabolised in fish. Conjugation and hydrolysis are important metabolization routes. Excretion is via gills and urine.

Environmental properties

Tricaine mesylate is downgraded in water under the influence of light within 14 days. Tricaine mesylate is soluble in water and is expected to be in the water until it downgrades. Under the influence of light this downgrading happens within 14 days. No available data indicates that the substance accumulates in aquatic organisms or in the food chain.

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.

The veterinary medicinal product can be mixed with equal amounts of sodium bicarbonate to buffer the anaesthetic solution, to ensure neutral pH.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

The stock solution must be used within the same day. Mixed anaesthetic solution must be changed several times during the day.

5.3 Special precautions for storage

Store in the original container.

Keep the container tightly closed in order to protect from light and moisture.

5.4 Nature and composition of immediate packaging

HDPE plastic box with sealed cover.

Pack sizes: 100 g
 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>.

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

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER(S)

{To be completed nationally}

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

{DD/MM/YYYY}

{To be completed nationally}

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

{To be completed nationally}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

{To be completed nationally}

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

HDPE plastic bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FINQUEL vet. 1000 mg/g powder for immersion, solution, anesthetic for Atlantic salmon, rainbow trout and experimentally for cod

2. STATEMENT OF ACTIVE SUBSTANCES

Tricaine mesylate 100%

3. PACKAGE SIZE

100 g
1000 g

4. TARGET SPECIES

Atlantic salmon, rainbow trout and experimentally for cod

5. INDICATIONS

For products not subject to veterinary prescription:
Sedation and anaesthesia of Atlantic salmon, rainbow trout and experimentally cod

6. ROUTES OF ADMINISTRATION

Immersion, solution.

7. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 25 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store in the original container.
Keep the container tightly closed in order to protect from light and moisture.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

{To be completed nationally}

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

FINQUEL vet. 1000 mg/g powder for immersion, solution, anesthetic for Atlantic salmon, rainbow trout and experimentally for cod

2. Composition

Active substance:

Tricaine mesylate 100%

White or almost white powder.

3. Target species

Atlantic salmon, rainbow trout, experimentally cod.

4. Indications for use

For sedation and anaesthesia of Atlantic salmon, rainbow trout and experimentally cod in relation to vaccination and handling (for example sorting, weighing, stripping etc.).

5. Contraindications

None.

6. Special warnings

Special warnings:

Safety of the veterinary medicinal product at temperatures $< 7\text{ }^{\circ}\text{C}$ and $> 17\text{ }^{\circ}\text{C}$ is not documented.

Special precautions for safe use in the target species:

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The veterinary medicinal product is irritating if it comes in contact with eyes, respiratory organs and uncovered skin.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. If contact with eyes, rinse with water and contact physician. Personal protective equipment consisting of gloves and dust mask should be worn when handling the veterinary medicinal product. Use gloves when handling the mixed product and avoid spillage in eyes and mouth.

In rare cases hypersensitive people and/or people with occupational overexposure may develop methemoglobinemia after contact with the veterinary medicinal product.

Special precautions for the protection of the environment:

If concentrated emissions to water occurs the water for the recipient must be sufficiently diluted.

Pregnancy and lactation:

Laboratory studies in minnow (*Pimephales promelas*) and rainbow trout (*O. mykiss*) have not produced any evidence of teratogenic, foetotoxic or maternotoxic effects.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose:

If overdose occurs the fish must be transferred to fresh water and assuring perfusion of the gills until normal respiration is restored.

Major incompatibilities:

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

The veterinary medicinal product can be mixed with equal amounts of sodium bicarbonate to buffer the anaesthetic solution, to ensure neutral pH.

7. Adverse events

Atlantic salmon, rainbow trout and experimentally for cod:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Dosage for salmon and rainbow trout:

Indication	Dosage mg/l	Maximum residence time in the anaesthetic solution	Recovery time after transfer to fresh water
Sedation	15 – 30	6 hours	-
Anaesthesia	50 – 60	30 minutes	2-20 hours
Fast anaesthesia	80 – 135	4 – 12 minutes	3 – 19 minutes

Dosage for cod:

Indication	Dosage mg/l	Maximum residence time in the anaesthetic solution	Recovery time after transfer to fresh water
Anaesthesia	50	5 minutes	Appr. 4 minutes

A solution of the desired concentration of Finquel is prepared in water, and the fish is kept in the solution until the desired anaesthetic is achieved.

9. Advice on correct administration

When used in fresh water the veterinary medicinal product has best effect if the anaesthetic solution is buffered with sodium bicarbonate to ensure neutral pH in the anaesthetic solution.

A stock solution of Finquel is made by weighing the powder needed and water is then added. The same method is used to make a stock solution of sodium bicarbonate. The stock solutions must be made separately and must not be mixed. The same amount of stock solution of both Finquel and sodium bicarbonate must be added to the anaesthetic tub. This will give a clear solution. When used in sea water buffering is not needed. The stock solution must be used the same day. The mixed anaesthetic solution must be changed several times during the day.

The anaesthetic solution must be oxygenated (7 mg/l).

The dosage is temperature-dependent. When the desired anaesthetic is achieved the fish must be moved to fresh water for recovery.

It is recommended to test the mixed anaesthetic solution on a smaller group of the representative fish.

10. Withdrawal periods

Meat and offal: 25 degree days. If cod is slaughtered within 21 days, the liver must be discarded.

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 light and moisture.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater <or household waste>.

{<> to be adjusted nationally}

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 applicable national collection systems. These measures should help to protect the environment.

<Ask your <veterinary surgeon> <or> <pharmacist> how to dispose of medicines no longer required.>

{<> to be adjusted nationally}

13. Classification of veterinary medicinal products

{<> to be adjusted nationally}

14. Marketing authorisation numbers and pack sizes

{<> MA no. to be adjusted nationally}

Pack sizes: 100 g, 1000 g.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

{<> to be adjusted nationally}

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder <,> <and> <manufacturer responsible for batch release> <and contact details to report suspected adverse events>:

{<> to be adjusted nationally}

Manufacturer responsible for batch release:

Curida AS

Solbærvegen 5

P.O. Box 1627

NO-2419 Elverum

Norway

<Local representatives <and contact details to report suspected adverse events>:>

{<> to be adjusted nationally}

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

{<> to be adjusted nationally}