

[Version 8.1,01/2017]

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 substance: tricaine mesylate

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for immersion, solution

White, crystalline powder.

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the 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.).

4.3 Contraindications

None.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

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

The 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 product.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

When used in fresh water the 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: anaesthetic.

ATC vet code: QN01 AX93.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Major incompatibilities

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

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

6.3 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.

6.4 Special precautions for storage

Store in the original container.

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

6.5 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.

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

02-1257

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 5.12.2006
Date of last renewal: 5.12.2016

10. DATE OF REVISION OF THE TEXT

22.02.2018

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

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. PHARMACEUTICAL FORM

Powder for immersion, solution

4. PACKAGE SIZE

100g or 1000 g

5. TARGET SPECIES

Atlantic salmon, rainbow trout and experimentally for cod

6. INDICATION(S)

Sedation and anaesthesia of Atlantic salmon, rainbow trout and experimentally cod

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Immersion, solution.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Meat and offal: 21 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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 light and moisture.

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

Dispose of waste material 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.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

02-1257

17. MANUFACTURER'S BATCH NUMBER

Batch

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

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

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

Marketing authorisation holder:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Manufacturer responsible for batch release:

Scan Aqua AS
Postboks 233
2151 Årnes

2. 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

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

Tricaine mesylate 100 %

4. INDICATION(S)

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. 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

Atlantic salmon, rainbow trout, experimentally cod.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 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.

Safety of the product at temperatures < 7 °C and > 17 °C is not documented.

10. WITHDRAWAL PERIOD(S)

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

11. SPECIAL STORAGE PRECAUTIONS

Store in the original container.

Keep the container tightly closed in order to protect from light and moisture.
Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

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

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

The 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 product.

Interaction with other medicinal products and other forms of interaction:

None known.

Overdose (symptoms, emergency procedures, antidotes):

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

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

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

22.02.2018

15. OTHER INFORMATION

Not all pack sizes may be marketed.
Pack sizes: 100 g, 1000 g.