PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calicide Teflubenzuron 1000 g/kg Premix for Medicated Feeding Stuff

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Technical Teflubenzuron 1,000 g/kg

3. PHARMACEUTICAL FORM

A white to off-white powder for mixing with pelleted feed

4. PACKAGE SIZE

1, 2, 5, 10 or 25 kg

5. TARGET SPECIES

Atlantic salmon

6. INDICATION(S)

Calicide is only effective against the developing (moulting) stages of sea lice.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The product is administered at a dose rate of 10 mg teflubenzuron per kilogram of bodyweight per day for 7 days. It is essential for all fish to receive adequate medicated feed for effective treatment. For incorporation into dry feed at the registered mill. A manufacturer who is approved to incorporate directly at any concentration, veterinary medicinal products or premixtures containing such products must be responsible for mixing when incorporation is less than 2 kg per tonne for final feed.

8. WITHDRAWAL PERIOD

7 days after last treatment

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet fully before use

Operator Warnings

Technical material: Use a scoop and wear impervious gloves, overalls, approved safety glasses and 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, when handling this product.

Medicated fish feed: Never use bare hands to pick up the medicated feed. Use a scoop, wear impervious gloves and 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 when administering the medicated feed.

Do not smoke, eat or drink whilst handling this product or handling medicated feed.

Wash hands after use of this product or medicated feed.

Precautions for use

Calicide is only effective against the developing (moulting) stages of sea lice. If adult lice are present, use of an appropriate adulticide is recommended prior to treatment with Calicide. This product is not authorised for clinical use at water temperature below 9°C. Use in brood stock has not been investigated. Do not use when fish are sick or anorexic.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Store below 25°C. Store in a dry place.

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

Dispose of unused product, packaging or waste medicated feed in accordance with guidance from your local waste regulation authority. Before administering Calicide the use must first apply for and obtain a consent for its discharge from the Scottish Environment Agency (SEPA) in Scotland or the Environment Agency in England and Wales. The appropriate agency must also be advised of the time and subsequently of the quantities used.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-V

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 reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Trouw (UK) Limited
Wincham
Northwich
Cheshire
CW9 6DF

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01973/4002

17. MANUFACTURER'S BATCH NUMBER

PACKAGE LEAFLET FOR:

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

Trouw (UK) Limited
Wincham
Northwich
Cheshire
CW9 6DF

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calicide Teflubenzuron 1000 g/kg Premix for Medicated Feeding Stuff

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

A white to off-white powder for mixing with pelleted feed containing technical teflubenzuron 1,000 g/kg

4. INDICATION(S)

Calicide is indicated for therapeutic use in Atlantic salmon (*Salmo salar)* for the control and therapeutic treatment of infestation by developing stages of the salmon louse (*Lepeophtherius salmonis).*

Calicide is only effective against the developing (moulting) stages of sea lice. If adult lice are present, use of an appropriate adulticide is recommended prior to treatment with Calicide. Calicide should not be administered until completion of the withsrawal period of previous treatments.

5. CONTRAINDICATIONS

Calicide is not a prophylactic treatment

6. ADVERSE REACTIONS

7. TARGET SPECIES

Atlantic salmon

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

For oral administration in fish feed.

Calicide medicated feed is given orally at a dosage of 10 mg teflubenzuron per kilogram wet bodyweight per day for 7 days. Feeding rate will vary according to

water temperature and size of fish. The required dose should be incorporated into 50-75% daily feed ration. Extra feeding requirement can be supplied by unmedicated feed.

Ensure adequate medication of all fish in the cage by good feeding practice but do not exceed the recommended dosage.

Calicide can be mixed with pelleted fish food which is then sprayed with fish oil to ensure adherence of teflubenzuron to the pellets or, dispersed in fish oil and then sprayed on to the pellets. Mixing should be carried out in a feed mill authorised to incorporate at levels below 2 kg per tonne.

For incorporation into dry feed at the registered mill.

A manufacturer who is approved to incorporate directly at any concentration, veterinary medicinal products or premixtures containing such products must be responsible for mixing when incorporation is less than 2kg per tonne for final feed.

9. ADVICE ON CORRECT ADMINISTRATION

This product is not authorised for clinical use in water temperatures below 9^{o}C

10. WITHDRAWAL PERIOD(S)

Fish must not be slaughtered for human consumption during treatment. Fish may only be slaughtered for human consumption 7 days after last treatment.

11. SPECIAL STORAGE PRECAUTIONS

[Pharmaceuticals ONLY - *The following statement should be included if there is an in-use shelf life (example: solution for injection)]*

Store below 25°C. Store in a dry place.

Shelf life after incorporation into meal or pelleted feed: 6 months

12. SPECIAL WARNING(S)

Use in brood stock has not been investigated.

Use in conjunction with other medicines has not been investigated.

Do not use when fish are sick or anorexic or where the appropriate amount of medicated feed is unlikely to be consumed.

For Animal Treatment Only

Operator Warnings

Technical material: Use a scoop and wear impervious gloves, overalls, approved safety glasses and 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, when handling this product.

Medicated fish feed: Never use bare hands to pick up the medicated feed. Use a scoop, wear impervious gloves and 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 when administering the medicated feed.

Do not smoke, eat or drink whilst handling this product or handling medicated feed.

Wash hands after use of this product or medicated feed.

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

Dispose of unused product, packaging or waste medicated feed in accordance with guidance from your local waste regulation authority. Before administering Calicide the use must first apply for and obtain a consent for its discharge from the Scottish Environment Agency (SEPA) in Scotland or the Environment Agency in England and Wales. The appropriate agency must also be advised of the time and subsequently of the quantities used.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

POM – V To be supplied only on veterinary prescription

Vm 01973/4002

Keep out of reach of children.

For use only under veterinary supervision.

Package quantities: 1, 2, 5, 10 and 25 kg drums. Not all pack sizes may be marketed.

Approved: 04/01/2018