SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Calicide, Teflubenzuron 1000g/kg. Premix for medicated feeding stuff.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition	Quantitative composition
Technical Teflubenzuron	1000 g/kg

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuff.

A white to off-white powder.

4. CLINICAL PARTICULARS

4.1 Target species

Atlantic salmon (*salmo salar)*

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

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

4.4 Special warnings for each target species

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

4.5 Special precautions for use

i. Special precautions for use in animals

Do not administer before completion of the withdrawal period of previous treatments.
The product has no residual activity and is only effective during the treatment period.
The product is effective only against the developing (moulting) stages of sealice. If adult lice are present, use of an appropriate topical

adulticide is recommended prior to start of treatment.

For oral administration is fish feed only.

The product is not suitable for prophylaxis.

ii. Special precautions for the person administering the veterinary medicinal product to animals

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.

iii. Other precautions

This product is not authorised for clinical use in water temperatures below 9ºC.

Before administering Calicide the user must first apply for and obtain a consent for its discharge from the Scottish Environment Protection Agency (SEPA) in Scotland or the Environment Agency (EA) in England and Wales. The appropriate agency must also be advised of the time of use and subsequently of the quantities used.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Use in broodstock has not been investigated.

4.8 Interaction with other medicinal products and other forms of interaction

Use in conjunction with other medications has not been investigated.

4.9 Amount(s) to be administered and administration route

The product is effective against developing (moulting) larvae and pre-adult stages of sea lice. Therefore pre-treatment with suitable ectoparasiticide is recommended to control adult sealice.

For incorporation into dry feed at the registered mill.

The product is sold ready for mixing with pelleted fish feed for oral administration. The product is administered at a dose rate of 10 mg teflubenzuron per kilogram body weight per day for 7 days. Mixing should be carried out in a feed mill authorised to incorporate at levels below 2 kg per tonne.

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.

It is important to ensure that all the medicated feed is consumed by all the fish in the cage. The required dose should be incorporated into 50-70% of daily feed ration and given as the first feed of the day using good feeding practice. Extra feeding requirements can be supplied using unmedicated feed.

The final pharmaceutical from is prepared either by mixing the product with pelleted feed, which is then sprayed with fish oil to ensure adherence of the teflubenzuron, or by dispersing it in fish oil and then spraying it onto the pelleted feed. The final pharmaceutical form administered to fish is a dry pellet.

Before administering the product the user must first apply for and obtain a consent for its discharge from the Scottish Environmental Protection Agency (SEPA) in Scotland or the Environment Agency (EA) in England and Wales. The appropriate agency must also be advised of the times of use, and subsequently of the quantities used.

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

Overdosing is unlikely to occur in practice, and no special warnings are required, if the recommended dosage is adhered to.

Target animal safety studies in which doses of up to 4.7 times the recommended dose and over 3 times the recommended duration were administered, indicated no adverse effects. Acute toxicity studies have shown that there are some reversible behavioural effects seen at dose rate of between 12 times and 20 times the therapeutic dose.

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:
Antiparasitic products, insecticides and repellents.

ATC Vet Code:

QP53BC03

5.1 Pharmacodynamic properties

Teflubenzuron is an insect growth regulator belonging to the benzoyl urea group of compounds. Teflubenzuron is active orally and interferes with chitin synthesis and the moulting process of sea lice.

5.2 Pharmacokinetic properties

Pharmacokinetic and metabolic studies have indicated that the oral bio availability of
on is approximately 9% , indicating incomplete absorption and low systemic exposure. After a single oral dose, T_{max} is between 9 and 24 hours, and C_{max} 150-572 ng/ml, being temperature related. Steady state plasma concentrations after multiple dosing are achieved by day 2.

Despite the low oral bioavailability, the absorbed material is rapidly distributed to the tissues. Highest concentrations of teflubenzuron are found in the gall bladder at 2 days and the liver at 9 hours. These high levels and the relatively long half-life in the liver (38 days) indicate enterohepatic recirculation, which is commonly seen in fish. Elimination is biphasic. In repeat oral dose studies at 10°C, the half-lives over the initial 24 hour phase were calculated to be 2.6 days for the kidney and 3.8 days for the skin and muscle combined.

5.3 Environmental properties

None known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Polyethylene bag, in either a steel or microfibre drum containing 25kg, or a polyethylene bag within polyethylene pail containing 1kg, 2kg, 5kg or 10kg, closed with a polyethylene push fit lid.
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, if appropriate

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Trouw (UK) Limited
Wincham
Northwich
Cheshire
CW9 6DF

8. MARKETING AUTHORISATION NUMBER(S)

Vm 01973/4002

9. DATE OF FIRST AUTHORISATION

Date: 18th August 1999

10. DATE OF REVISION OF THE TEXT

Date: March 2009