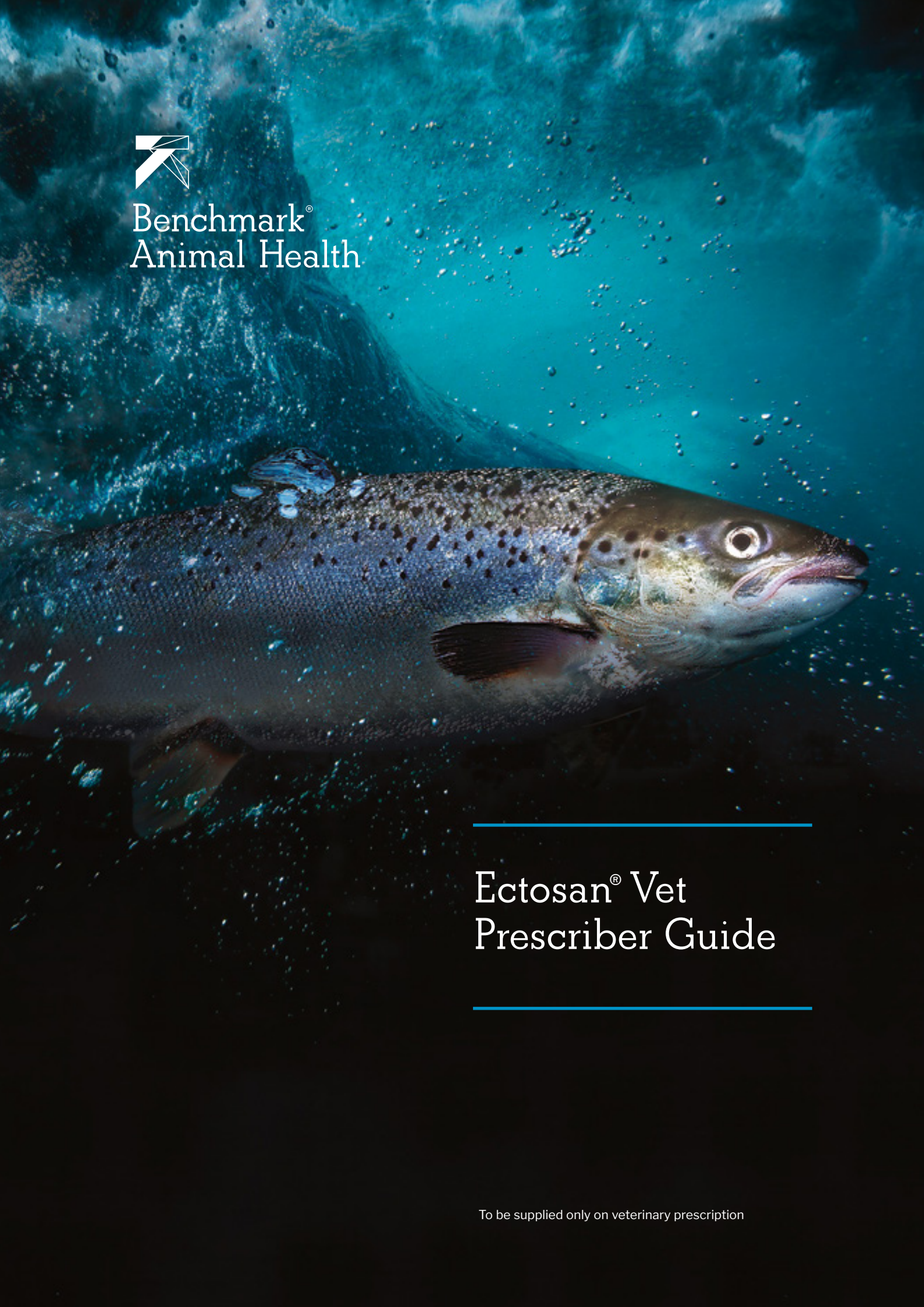


Benchmark®
Animal Health

Ectosan® Vet Prescriber Guide

To be supplied only on veterinary prescription

Ectosan® Vet is a veterinary medicine for treatment of pre-adult and adult sea-lice *(Lepeophtheirus salmonis)* on Atlantic salmon *(Salmo salar)* and Rainbow trout *(Oncorhynchus mykiss)*. The active ingredient is imidacloprid and the treatment dose is 20 mg Ectosan® Vet per litre of sea water for a period of 60 minutes. Ectosan® Vet has been developed for use exclusively in wellboats, allowing for the retention and subsequent purification of the treatment water, via CleanTreat®.

The retention of treatment water also facilitates the reuse of treatment water, allowing for the treatment of multiple batches of fish.

CleanTreat® has been developed as a platform solution to prevent environmental impact from bath treatments used in Aquaculture. Ectosan® Vet **must** only be used with a purification system such as CleanTreat®, ensuring the treatment water is purified prior to discharge. CleanTreat® facilitates bath treatments to be used with the highest regard for the environment. Together, Ectosan® Vet and CleanTreat® signify an industry benchmark in the administration of anti-parasitic medicines in salmon production, allowing for greater environmental stewardship while effectively controlling sea lice.

To ensure sustainable and effective long-term lice management within aquaculture, Ectosan® Vet should be used as part of a strategic integrated pest management (IPM) strategy to effectively control sea lice. The IPM strategy should manage sea lice with a systematic and holistic approach and consider all available preventative and reactive measures to ensure optimal sea lice management.

This guide details relevant product information to support Prescribers when assessing treatments with Ectosan® Vet. The Summary of Product Characteristics (SPC), package leaflet and the Material Safety Data Sheet (MSDS) must have been read and understood by all operatives who will be carrying out treatments with Ectosan® Vet.

The treatment procedure is the responsibility of the prescribing veterinarian or fish health biologist, and this guidance document does not change that responsibility. Please refer to the SPC and the MSDS for further treatment and product safety information.

List of Definitions

Name	Definition
Codex	The Codex Alimentarius is an international code of food standards developed by the Codex Alimentarius Commission (Codex), under the United Nations, as a joint program of the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). The food safety standards, guidelines, and recommendations established by Codex are the official food safety references used by the World Trade Organization (WTO) in international trade disputes.
Material Safety Data Sheet (MSDS)	Lists the hazardous ingredients of a product, its physical and chemical characteristics (e.g., flammability, explosive properties), its effect on human health, the chemicals with which it can adversely react, handling precautions, the types of measures that can be used to control exposure, emergency and first aid procedures, and methods to contain a spill.
Maximum Residue Limit (MRL)	The maximum residue limit (MRL) is the maximum allowed concentration of residue in a food product obtained from an animal that has received a veterinary medicine or that has been exposed to a biocidal product for use in animal husbandry. The Ectosan® Vet MRL is 600 µg/kg.
Package Leaflet	The leaflet in every 2 x 100 g and 1 x 1000 g pack of medicine that contains information on the medicine for the end-user as per the SPC.
Package Label	The label on every 10 x 1000 g pack of medicine that contains information on the medicine for the end-user as per the SPC.
Summary of Product Characteristics (SPC)	A description of a medicinal product's properties and the conditions attached to its use. It explains how to use and prescribe a medicine.
Spillage	Any volume of water containing active ingredient which does not undergo processing through CleanTreat® and/or the spill or loss of the product in its powdered form and/or the spill or loss of the product as packaged. Including but not limited to spillage on deck or overboard, leakage from broken or faulty hosing, pipework, equipment or other and accidental release from wells or pipework.
Withdrawal Period	The minimum period of time between treatment and the production of meat or other animal-derived products for food.
Total exposure time	The maximum theoretical time fish can be exposed to Ectosan® Vet. For single use this is the combined treatment time and unloading time. For reuse this is the combined loading time, treatment time and unloading time.
Norwegian Medicine Agency (NoMA)	The national, regulatory authority for new and existing medicines and the supply chain in Norway. The agency is responsible for supervising the production, trials and marketing of medicines.

Contents

1 Health, Safety and Environment

It is the responsibility of the user of this product to develop and implement the control measures necessary for its safe use and to prevent release to the environment. These control measures should be identified as part of a risk assessment process in accordance with local legal requirements.

2 Ectosan® Vet Prescription Support

Accurately calculate and order the correct quantity of product in the correct presentation for treatment. E.g., a well volume of 3600 m^3 split over two wells of 1800 m^3 will require 36 kg per well (72 kg total), requiring 6 x 10 kg presentation and 12 x 1 kg presentations per treatment.

If the treatment water is to be reused and the wellboat uses an overpressure system to unload fish, for which a known volume of water is added to the treatment wells, a dose top-up will be required to account for the dilution and medicine should be ordered accordingly.

Assess water volume within the treatment well as accurately as possible when calculating the amount of product needed for treatment to avoid suboptimal dosing.

To achieve a final concentration of 20 mg imidacloprid /L, 20 g of Ectosan® Vet per m^3 of seawater is required (20g x well volume (m^3)). The following amount (litres) of seawater are necessary to achieve the recommended dose with the respective pack sizes:

Package Size	Capacity (m^3)	Litres of Water (L)
200 gram (2 x 100 gram)	10	10.000
1000 gram (1 x 1000 gram)	50	50.000
10 kg (10 x 1000 gram)	500	500.000

The dose for each treatment well must be prepared separately. As part of Benchmark Technical Services (see *Technical Services, page 06*) Benchmark have dedicated wellboat specialists that train, assess and audit wellboat crews in the correct administration and treatment procedure with Ectosan® Vet.

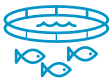
It is essential to ensure Ectosan® Vet is used according to the SPC and therefore the Ectosan® Vet treatment sheet (TEC-FRM-07) should be used for each treatment to ensure best practices are maintained. This will be provided by the dedicated wellboat specialist and can be obtained by contacting Benchmark, see *Useful Contacts, page 10.*

Please contact Benchmark for further information and support.

3 Technical Services

Benchmark Animal Health offers a comprehensive Technical Services Programme including a dedicated and experienced team to provide treatment support throughout treatments at all stages, supporting treatment optimisation and developing product best practices.

INTEGRATED TECHNICAL SUPPORT



Pre-Treatment

- Treatment planning & optimisation
- Risk assessment support
- Wellboat assessment, training & support
- Environmental monitoring
- Sensitivity assessment

During Treatment

- Treatment support & troubleshooting
- Animal welfare evaluation
- Efficacy evaluation

Post Treatment

- Environmental monitoring
- Sensitivity monitoring
- Customer report
- Medicine reconciliation

3.1 Customer and Wellboat Treatment Guidance and Support

Customer and wellboat support will be available at the pre-treatment stage to assess and validate wellboats for treatment, inclusive of wellboat crew training and assessment in the complete Ectosan® Vet treatment procedure, coordinate zone and treatment scheduling, considering all relevant factors, including CleanTreat®. Relevant biosecurity documents will also be made available prior to treatment and support given for facilitating veterinary Inspections when necessary.

During treatment, 24 hour communication will be available to provide urgent and non-urgent support along with relevant troubleshooting. Benchmark Technical Services representatives can also be available on-site for treatments upon customer request. Post-treatment provision of customer reports, treatment evaluations and feedback will ensure all relevant documentation is complete and support the continuous development of Ectosan® Vet best practices.

To ensure wellboat dose continuity and treatment optimisation, Benchmark will monitor the treatment dose concentration of Ectosan® Vet when a new wellboat carries out treatments with Ectosan® Vet. A minimum of 10 consecutive treatments following the dosing of treatment wells will be monitored.

3.2 Sensitivity Monitoring Programme

Benchmark are committed to effectively monitoring the sensitivity of sea lice to Ectosan® Vet to allow any changes in sensitivity to be detected, allowing effective action plans to be implemented to maintain treatment efficacy.

Benchmark Technical Services can support customers to carry out sensitivity assessments and implement relevant action plans to maintain treatment efficacy. The aim of the Sensitivity Monitoring Programme is to focus on preventative measures to maintain lice sensitivity to Ectosan® Vet, ensuring optimum treatments for the customer.

Sensitivity monitoring should be carried out if a site is considering re-treating with Ectosan® Vet.

3.3 Environmental Monitoring Programme

As part of its commitment to environmental stewardship, Benchmark will monitor the environmental fate of any residues of Ectosan® Vet released into the environment. Environmental monitoring will be undertaken at a number of selected sites that undergo treatment with Ectosan® Vet.

The Environmental Monitoring Programme will be coordinated by Benchmark Technical Services at both the farm site and CleanTreat® vessel, in which sediment and water sampling for chemical analysis will be collected. Pre-treatment monitoring will allow a baseline of concentrations to be established in the environment and post-treatment monitoring at several timepoints will allow the environmental fate of Ectosan® Vet to be monitored.

4 Storage of Ectosan® Vet

Storage facilities for Ectosan® Vet must meet the following conditions:

- Store in a secured storage facility.
- Store in a dry place in the original unopened packaging.
- Store away from food, drink or animal feeding stuffs.
- Protect from direct sunlight.

Ectosan® Vet must be stored between 5 °C and 25 °C with temperature loggers and meet the requirements as per above to allow product return.

5 Tissue Residues and Export of Treated Fish

The MRL for Ectosan® Vet in the EU, EAA, UK and the Faroe Islands is 600 µg/kg and as per the SPC, the withdrawal period is 98 degree-days. This is applicable for total exposure times of up to 6 hours.

5.1 Extended exposure of greater than 6 hours

If total exposure exceeds 6 hours, it is recommended as per the SPC to extend the withdrawal period. For guidance, the data used to set the withdrawal period has been extrapolated and the withdrawal period calculated. The following is provided as guidance only and it is recommended that residue assessments are carried out prior to harvest.

Total Exposure time	Withdrawal Period Recommended for residues ≤ 600 µg/kg
6 hours	98 degree days
7 hours	104 degree days
8 hours	112 degree days
9 hours	120 degree days

In all cases of extended exposure exceeding 6 hours please speak to your Benchmark representative for further guidance, see *Useful Contacts (page 10).*

5.2 Export outside of the European Union/The Faroe Islands

For countries inside the EU, an MRL has been approved of 600 µg/kg, this has also been adopted by the UK. The USA has an approved import tolerance of 0.6 ppm (600 µg/kg) in concurrence with the EU MRL. An application has been made for an import tolerance in Japan, and an application has been made to Codex for an international veterinary medicine MRL that will be recognised by all participating nations.

For export of fish treated with Ectosan® Vet to countries outside of the European Union and the Faroe Islands that do not have an established MRL or import tolerance for imidacloprid, it is recommended that a zero residues approach is taken for fish to be exported to countries without an approved MRL (residues below limit of quantification (LOQ) of residue assay). The LOQ for the residue assay is 4 µg/kg. If this approach is to be taken the withdrawal period must be extended. The withdrawal period to be used in this instance would be 398 degree days. This is calculated using the European Medicines Agency withdrawal period calculation software that was used to set the withdrawal period on the SPC. It is also recommended that fish are sampled for residues prior to harvest if they are intended for export outside of the EU, Faroe Islands or the USA, to countries without an approved MRL. Please contact your BMK representative for support in carrying out residue assessments.

Imidacloprid is also used in pesticides and there are pesticide MRL set for many food commodities in some countries. It should be noted that the calculation of MRLs for pesticides is different to veterinary medicines and that these MRL levels are not a reflection of the MRL that may be set following an import tolerance or Codex application.

6 Waste

Any unused drug, drug residues and packaging shall be disposed of in accordance with local requirements.

All waste collected during filtration and the treatment process must be disposed of as special waste.

7 Pharmacovigilance (PV) Reporting

It is requested that all suspected Adverse Events be reported to **BENCHMARK® ANIMAL HEALTH** no later than 24 hours after the occurrence of the incident. This includes the following types of Suspected Adverse Event, and should be reported regardless of whether the product has been used according to the product label or not:

- Suspected Adverse Events in fish such as an increase in expected mortality, or adverse reactions such as lethargy, gasping, orientation problems, balance problems, erratic swimming.
- Adverse Events in humans such as accidental exposure of an operator to the product.
- Suspected lack of expected efficacy (SLEE) of the product.
- Suspected environmental adverse events, including any accidental spillage of the product, water containing the product or waste relating to the product into the environment, or any discharge of treatment water above agreed threshold levels.
- Suspected breach of residue limits in the fish post-harvest.

In addition, any complaints that relate to the quality or any other unexpected incident received in relation to the products should be reported to **BENCHMARK® ANIMAL HEALTH** no later than **24 hours** after occurrence of the incident.

The minimum information requested is as follows:

- An identifiable reporter (wherever possible including name and address of the original reporter) – this can be anonymised if requested.
- Animal/human details (i.e., species and/or sex and/or age) or the affected environment.
- Suspected product (brand name and marketing authorisation holder).
- Adverse event details.

All suspected adverse events should be reported either via **BENCHMARK® ANIMAL HEALTH** or can be reported direct to the regulatory authority.

If you are based in Norway, either contact Benchmark® Animal Health or contact NoMA directly with Adverse Event reports.

Benchmark® Animal Health
Norway: +47 94 17 78 10
E-mail: *pv@bmkanimalhealth.com*
Web: bmkanimalhealth.com

Norwegian Medicines Agency
Norway: +47 22 89 77 00
E-mail: *vet.felles@legemidelverket.no*
Web: legemiddelverket.no

8 Useful Contacts

For any further information or support please contact Benchmark® Animal Health.

Norway

ectosanvet@bmkanimalhealth.com

(+47) 94 17 78 10

For urgent and non-urgent communication contact your local Benchmark® Animal Health representative.

Ectosan® Vet
CleanTreat®