[Version 8, 10/2012]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ASPERIX Vet, 49.5 % w/w hydrogen peroxide concentrate for solution for fish treatment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
49.5 % w/w Hydrogen Peroxide

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for solution for fish treatment.
The solution is a clear, colourless liquid.

4. CLINICAL PARTICULARS

4.1 Target species

Atlantic salmon (*Salmo salar)*

4.2 Indications for use, specifying the target species

For the treatment of salmon suffering from infestation with motile (pre-adult to adult) sea lice, *Lepeophtheirus salmonis* or *Caligus spp,* prior to the stage where serious tissue damage occurs.

4.3 Contraindications

Do not exceed the recommended concentration of hydrogen peroxide.

Do not use at high water temperatures.

Extreme care should be taken if using hydrogen peroxide at water temperatures above 14°C. If treatment is unavoidable, hydrogen peroxide concentration and contact time should be reduced. If signs of atypical behaviour, e.g. fish losing equilibrium or hyperactivity are observed, treatment should be stopped immediately.

Do not use in fish with a mean weight of less than 200 g.

Do not treat fish which are showing clinical signs of previous gill damage.
An assessment of gill condition and the possibility of other stressors e.g. algal blooms should be made before commencement of treatments.

Do not use in stressed fish.

4.4 Special warnings for each target species

Repeated use of the same chemotherapeutic agent may encourage the development of resistance to the agent.

4.5 Special precautions for use

Special precautions for use in animals

If problems occur when raising nets or setting the tarpaulin extending the time that fish are constricted within the treatment bath, extra care should be taken as fish may be unduly stressed prior to hydrogen peroxide addition.

In the event that fish begin to lose their equilibrium and possibly begin to sink during treatment with hydrogen peroxide, tarpaulins must be removed immediately. Residual hydrogen peroxide should be flushed from the cage using the wash from a boat.

Oxygen sparges should remain in the cage even if they are not used during treatment. This provides the ability to agitate moribund fish preventing them settling on the floor of the net. Affected fish should recover after a short period when nets may be dropped to their full extent.

If during treatment with hydrogen peroxide fish become hyperactive, this may be indicative of increased hydrogen peroxide concentrations or that fish have become unduly stressed.

Hydrogen peroxide concentration may be tested with a suitable test method and dissolved oxygen should be monitored to prevent an oxygen crash occurring. In the event that the hydrogen peroxide and dissolved oxygen concentration are normal but hyperactivity persists, treatment should be stopped. This should prevent a subsequent oxygen crash and minimise scaling of fish.

The nets should be partially lowered to increase the volume of water available to the fish and hydrogen peroxide residuals should be flushed away using the wash from a boat. These actions should relieve any undue stress to the fish.
The activity of the fish should be allowed to return to normal before the nets are completely dropped.

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

Harmful

Corrosive

Oxidising Agent

Do not attempt to administer the product unless you have been fully trained to handle and use the product, and are fully aware of operational and safety procedures. Hydrogen peroxide is corrosive.

This product is harmful if swallowed or if inhaled and may cause respiratory irritation. Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.

Avoid contact with skin and eyes. This product may cause skin irritation and serious eye damage.

Wear personal protective equipment whilst handling this product, consisting of chemically resistant headgear, face shield or safety goggles, chemically resistant PVC acid suit/ oilskins, chemically resistant PVC gloves (with cuff under suit) and safety rubber boots (with suit over boots).

Before commencing handling of this product ensure a supply of fresh water and preferably eye wash solutions are available.

IN CASE OF INHALATION: Remove person to fresh air and keep comfortable for breathing. If you feel unwell SEEK IMMEDIATE MEDICAL ATTENTION by calling a physician or National Poisons Information Centre.

IN CASE OF ACCIDENTAL EYE CONTACT: Rinse immediately with plenty of clean water for several minutes. SEEK IMMEDIATE MEDICAL ATTENTION by calling a physician or National Poisons Information Centre. Remove any contact lenses, if easy to do so and continue rinsing eyes.

IN CASE OF ACCIDENTAL SKIN CONTACT: Immediately remove any contaminated clothing. Wash the exposed skin immediately with water and seek medical advice if irritation persists. Thoroughly clean the contaminated clothing by soaking with plenty of water before re-using.

IN CASE OF ACCIDENTAL INGESTION: Seek medical attention immediately and show the package leaflet or the label to the physician.

Always wash hands with soap and water directly after use.

Other precautions

Depending on regional requirements, the user may need to apply for and obtain consent for discharge. Check with the relevant regional legislative body e.g. SEPA in Scotland.

The most important mechanisms for removal of hydrogen peroxide in coastal waters is dilution and degradation which are increased by water movements including the flushing effects in sea lochs. Do not use at times of slack water as poor dilution and dissociation of residuals may occur.
After treatment care should be taken to provide sufficient water through the net to dilute residual hydrogen peroxide. The water from a boat's propeller may be used to increase water exchange in cases where low water exchange rates cannot be avoided. These measures will help to prevent possible adverse effects on aquatic life.

Do not allow concentrated product to contaminate wood, paper, grass or any other combustible materials as this may cause fire.

A water hose or other plentiful water supply should be available to dilute any spills and leaks of the product.

Do not return any product to original container.

Use clean and vented containers to retain any spilled product.

4.6 Adverse reactions (frequency and seriousness)

Adverse reactions with the product are rare.

Any cellular damage to the gill during treatment is transient and reparable. See section 4.3.

However, common signs that an adverse reaction is occurring include: fish losing equilibrium and possibly sinking, and fish becoming hyperactive which may as a result of increased hydrogen peroxide concentrations or increasing fish stress levels.

Measures to treat fish undergoing adverse reactions are detailed in section 4.5.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

Hydrogen peroxide should not interact with other medicaments as it is not systemic and is purely a physical treatment. If fish are stressed due to over handling or

disease, any form of lice treatment would produce further stress. However, this may be less detrimental than the lice burden.

Where medicaments have been given and gill function may be compromised, hydrogen peroxide should not be administered.

Refer to section 4.5 for further information.

4.9 Amounts to be administered and administration route

For external use only.

As the volume of water enclosed within the tarpaulin, temperature and duration of treatment impact on efficacy, the dosing instructions and regimen should be adhered to.

By total enclosure method at a concentration of approximately 1500 mg/L as hydrogen peroxide for a maximum of 20 minutes contact.

Infested fish should be bathed in 1500 mg/L hydrogen peroxide for a period of between 15 and 20 minutes. The contact time being dependent on the final concentration of hydrogen peroxide. The contact time should be decreased as water temperature exceeds 14°C.

The product is administered by the total enclosure method in which the fish cage net is raised to an approximately depth, e.g. 2 m. Then a tarpaulin is drawn beneath the net to produce the treatment bath. When this procedure has been accomplished, checks should be made to ensure that fish do not become trapped within folds of the net. Sufficient oxygen diffusers should be placed in the treatment enclosure to support the number and size of fish present. Oxygen should now be applied to the system.

Care should be taken when setting the tarpaulin so as not to unduly reduce the volume of the treatment bath. If fish treatment densities are too high, scaling and hyperactivity may occur. A suggested maximum treatment density would be 150 kg/m^3 but this would be dependent on fish size, year class etc. Fish must not be fed for at least 24 hours prior to treatment.

If nets are heavily fouled, care should be taken when using hydrogen peroxide. Bottle weights should be applied around the periphery of the treatment bath to prevent flotation of the net. These should be applied before commencing the treatment.

The estimated volume of the product to produce the treatment concentration of approximately 1500 mg/L hydrogen peroxide should now be administered using safe and compatible dosing equipment.

To achieve an effective concentration of 1500 mg/L in a cage, approximately 2.6 litres of the product will be needed for every metre cube of water to be treated.

The following steps should be followed before treatment commences.

1. Assess the water volume to be treated in m^3.

2. Multiply the water volume by 2.55 to obtain the volume in litres of product required to achieve a concentration of 1500 mg/L hydrogen peroxide.

3. Add the product to the cage using dedicated dosing equipment.

4. Once the addition is completed, a sample of the treated water should be taken and analysed immediately to obtain the confirmation of concentration in the cage.

   Samples of water should be taken at several points to assess the concentration of the treatment solution using a suitable test method.

   If the treatment concentration is found to be low, sufficient hydrogen peroxide should be added to achieve the treatment concentration.

   The required volume of product to be added may be estimated from the following table:

   a) Locate the concentration as measured on assay in the row across the top.

   b) Proceed down this column to reach the row associated with the initial estimated volume.

   c) The resulting figure gives the additional volume to be added to the pen.

Estimated water volume (m^3)	Volume of ASPERIX Vet to add (L)	Additional volume ASPERIX Vet to add in litre if reading is (mg/L)							
		700	800	900	1000	1100	1200	1300	1400
25	64	73	56	42	32	23	16	10	5
50	127	146	111	85	64	46	32	20	9
75	191	218	167	127	95	69	48	29	14
100	255	291	223	170	127	93	64	39	18
125	318	364	279	212	159	116	80	49	23
150	382	437	334	255	191	139	95	59	27
175	446	509	390	297	223	162	111	69	32
200	509	582	446	340	255	185	127	78	36
225	573	655	501	382	286	208	143	88	41
250	637	728	557	424	318	231	159	98	45
275	700	800	613	467	350	255	175	108	50
300	764	873	668	509	382	278	191	118	55
325	828	946	724	552	414	301	207	127	59
350	891	1019	780	594	446	324	223	137	64
375	955	1091	836	637	477	347	239	147	68
400	1019	1164	891	679	509	370	255	157	73
425	1082	1237	947	722	541	394	271	167	77
450	1146	1310	1003	764	573	417	286	176	82
475	1210	1382	1058	806	605	440	302	186	86
500	1273	1455	1114	849	637	463	318	196	91
750	1910	2183	1671	1273	955	694	477	294	136
1000	2546	2910	2228	1698	1273	926	637	392	182
2000	5093	5821	4456	3395	2546	1852	1273	784	364
3000	7639	8731	6684	5093	3820	2778	1910	1175	546
5000	12732	14551	11141	8488	6366	4630	3183	1959	909

If treatment concentration is high, the contact time may be reduced or the tarpaulin should be dropped. A contact time of between 15-20 minutes should prove sufficient for effective removal of lice.

Measurement of the concentration of hydrogen peroxide in solution should be continued during treatment and after the tarpaulin has been removed to ensure efficient dispersion has occurred.

During the treatment, fish must be observed for any signs of atypical behaviour. If fish appear distressed, e.g. losing equilibrium or becoming hyperactive during treatment, remove the tarpaulin and lower the net. Reference should be made to section 4.5.

After treatment ensure that residual hydrogen peroxide is dispersed in the local vicinity as quickly as possible, perhaps using the wash of a boat propeller.

Commercially available test kits may be used to monitor low levels of residual hydrogen peroxide.

A second application may be required (dependent on routine lice monitoring), to ensure the removal of previous surviving chalimi, which will have moulted through to

pre-adult stages. Care should be taken not to allow a build-up of mature lice as resettlement of copepodids could occur.

Where possible, treatments should be conducted during periods of high tidal flow to ensure good dispersal of residual hydrogen peroxide and dislodged lice. This will minimise any possible resettlement of lice.

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

An overdose situation may occur by two methods:

1. Addition of too much hydrogen peroxide to the treatment bath producing a higher concentration than recommended.
   In this event refer to contraindications and warnings.

2. Extended contact period above the recommended 15-20 minutes. This may be due to the poor dispersion of hydrogen peroxide after treatment.
   In this event refer to contraindications and warnings.

   Strong solutions of hydrogen peroxide produce irritation and “burning” of skin and mucous membranes or gills.

   Emergency procedures: remove tarpaulins immediately and flush hydrogen peroxide from the cage using the wash from a boat.

4.11 Withdrawal period(s)

Meat: Zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Dermatological; antiseptics and disinfectant
ATCvet code: QD08AX01

5.1 Pharmacodynamic properties

Water containing hydrogen peroxide may diffuse into the body of the lice or be drawn into the gut by normal biological processes, e.g. feeding.
Once within the body of the louse, dissociation of the hydrogen peroxide to oxygen and water may cause temporary or permanent disruption to internal structures, causing the parasite to detach from the host.

Reduced sensitivity of sea lice has been reported after repeated use of hydrogen peroxide. The proposed mechanisms of resistance were genetic selection of individuals with cuticle that provides a barrier to penetration by hydrogen peroxide or the presence of detoxifying enzymes. The requirements of national resistance monitoring programmes should be followed.

5.2 Pharmacokinetic particulars

Absorption:
As hydrogen peroxide is administered typically as a 20 minute bath treatment, absorption by the host is considered to be negligible.

Distribution:
Not applicable.

Biotransformation:
The possibility of any biotransformation is small, due to the unlikelihood of absorption occurring, and hydrogen peroxide being broken down by catalase and other enzymes. These may be considered as natural routes of detoxification and would occur very rapidly.

Elimination:
As above, break down of any hydrogen peroxide residual would be enzymatic. Excretion of hydrogen peroxide would not occur.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium dihydrogen diphosphate
Nitric acid
Deionised water

6.2 Incompatibilities

Keep away from acids, alkalis, reducing agents and metal salts.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 12 months

6.4. Special precautions for storage

Store in the original container.
Do not return product to original container.
Store in a secure place and out of reach of children
Do not store above 25 °C.
Protect from direct sunlight. Store away from heat sources.

6.5 Nature and composition of immediate packaging

Reusable stainless steel ISO-container with the capacity of 25 m^3 (25 000 litres).

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Harmful to aquatic life. Do not contaminate water courses or confined inlets with concentrated product as high concentrations may be deleterious to some marine species.

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

Evonik Operations GmbH
Rellinghauser Str. 1-11
45128 Essen
Germany

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}><{DD month YYYY}.>

10 DATE OF REVISION OF THE TEXT

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II*[Not applicable for MRP/DCP]*

A. <MANUFACTURER<S> OF THE BIOLOGICAL ACTIVE SUBSTANCE<S> AND> MANUFACTURER<S> RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

<D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION>

A. <MANUFACTURER<S> OF THE BIOLOGICAL ACTIVE SUBSTANCE<S> AND> MANUFACTURER<S> RESPONSIBLE FOR BATCH RELEASE

<Name and address of the manufacturer<s> of the biological active substance<s>

{Name and address}>

Name and address of the manufacturer<s> responsible for batch release

{Name and address}

<The printed package leaflet of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.>

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

<Veterinary medicinal product subject to prescription.>
<Veterinary medicinal product not subject to prescription.>

<According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

a) the administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) the disease to which the product is intended to confer immunity is largely absent from the territory in question.>

<Official control authority batch release is required for this product.> *[only for those immunological veterinary medicinal products which are listed for Official Control Authority Batch Release (OCABR) in accordance with Article 82 of Directive 2001/82/EC as amended.]*

Field Cod

C. STATEMENT OF THE MRLs

<Not applicable.>

[For pharmaceutical products]

The active substance<s> in {name of the product} <is><are> <an> allowed substance<s> as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification

<The excipients listed in section 6.1 of the SPC are <either> <allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required> <or> <considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product>.>

[In case of MRLs not been published yet]

The Committee for Medicinal Products for Veterinary Use has recommended the inclusion of {name of the active substance(s)} in {name of the product} in table 1 (Allowed substances) of the annex to Commission Regulation (EU) No 37/2010 as follows:

Pharmacologically active substance	Marker residue	Animal species	MRLs	Target tissues	Other provisions	Therapeutic classification

<The excipients, listed in section 6.1 of the SPC are <either> <allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required> <or> <considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product>.>

[For immunological products]

The active substance being a principle of biological origin intended to <produce> <active><passive><diagnose a state of> immunity is not within the scope of Regulation (EC) No 470/2009.

<The excipients (including adjuvants) listed in section 6.1 of the SPC are <either> <allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required> <or> <considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product>.>

<D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

<Specific pharmacovigilance requirements:>

<The periodic safety update report (PSUR) cycle should be restarted for submission of 6 monthly reports (covering all authorised presentations of the product) for the next two years, followed by yearly reports for the subsequent two years and thereafter at 3 yearly intervals. The data lock point (DLP) for the next PSUR would be {add DLP}.>*[Only applicable, if justified after authorisation.]*

· CONDITIONS OR RESTRICTIONS WITH REGARD TO THE SAFE AND EFFECTIVE USE OF THE MEDICINAL PRODUCT

· <SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE MARKETING AUTHORISATION UNDER EXCEPTIONAL CIRCUMSTANCES>

<This being an approval under exceptional circumstances and pursuant to Article 39(7) of Regulation (EC) No 726/2004, the MAH shall conduct, within the stated timeframe, the following measures:

Description	Due date

>

· <OBLIGATION TO CONDUCT POST-AUTHORISATION MEASURES>

<The MAH shall complete, within the stated timeframe, the following measures:

Description	Due date

>>

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

ISO Container

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ASPERIX Vet, 49.5 % w/w hydrogen peroxide concentrate for solution for fish treatment
Hydrogen peroxide

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Hydrogen peroxide 49.5 % w/w

3. PHARMACEUTICAL FORM

Concentrate for solution for fish treatment

4. PACKAGE SIZE

25 m^3 (25 000 litres)

5. TARGET SPECIES

Atlantic salmon (*Salmo salar)*

6. INDICATION(S)

For the treatment of salmon suffering from infestation with motile (pre-adult to adult) sea lice, *Lepeophtheirus salmonis* or *Caligus spp,* prior to the stage where serious tissue damage occurs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

8. WITHDRAWAL PERIOD

Meat: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Do not attempt to administer the product unless you have been fully trained to handle and use the product, and are fully aware of operational and safety procedures.
Read package leaflet for full warnings.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store in the original container.
Do not return product to original container.
Store in a secure place and out of reach of children.
Do not store above 25 °C.
Protect from direct sunlight.
Store away from heat sources.

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

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"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Evonik Operations GmbH
Rellinghauser Str. 1-11
45128 Essen
Germany

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
ASPERIX Vet, 49.5 % w/w hydrogen peroxide concentrate for solution for fish treatment

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

Marketing authorisation holder:
Evonik Operations GmbH
Rellinghauser Str. 1-11
D-45128 Essen
Germany

Manufacturer responsible for batch release:
Evonik Antwerpen N.V.
Tijsmanstunnel West
B-2040 Antwerpen
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ASPERIX Vet, 49.5 % w/w hydrogen peroxide concentrate for solution for fish treatment
Hydrogen Peroxide

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

Active substance:
49.5 % w/w Hydrogen Peroxide

Excipients:
Disodium dihydrogen diphosphate
Nitric acid
Deionised water

The solution is a clear, colourless liquid.

4. INDICATION(S)

For the treatment of salmon suffering from infestation with motile (pre-adult to adult) sea lice, *Lepeophtheirus salmonis* or *Caligus spp,* prior to the stage where serious tissue damage occurs.

5. CONTRAINDICATIONS

Do not exceed the recommended concentration of hydrogen peroxide.

Do not use at high water temperatures.

Extreme care should be taken if using hydrogen peroxide at water temperatures above 14°C. If treatment is unavoidable, hydrogen peroxide concentration and contact time should be reduced. If signs of atypical behaviour, e.g. fish losing equilibrium or hyperactivity are observed, treatment should be stopped immediately.

Do not use in fish with a mean weight of less than 200 g.

Do not treat fish which are showing clinical signs of previous gill damage.
An assessment of gill condition and the possibility of other stressors e.g. algal blooms should be made before commencement of treatments.

Do not use in stressed fish.

6. ADVERSE REACTIONS

Adverse reactions with the product are rare.

Any cellular damage to the gill during treatment is transient and reparable. However, common signs that an adverse reaction is occurring include: fish losing equilibrium and possibly sinking, and fish becoming hyperactive which may as a result of increased hydrogen peroxide concentration or increasing fish stress levels.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Atlantic salmon (*Salmo salar)*

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

For external use.

As the volume of water enclosed within the tarpaulin, temperature and duration of treatment impact on efficacy, the dosing instructions and regimen should be adhered to.

By total enclosure method at a concentration of approximately 1500 mg/L as hydrogen peroxide for a maximum of 20 minutes contact.

Infested fish should be bathed in 1500 mg/L hydrogen peroxide for a period of between 15 and 20 minutes. The contact time being dependent on the final concentration of hydrogen peroxide. The contact time should be decreased as water temperature exceeds 14°C.

The product is administered by the total enclosure method in which the fish cage net is raised to an approximately depth, e.g. 2 m. Then a tarpaulin is drawn beneath the net to produce the treatment bath. When this procedure has been accomplished, checks should be made to ensure that fish do not become trapped within folds of the net. Sufficient oxygen diffusers should be placed in the treatment enclosure to support the number and size of fish present. Oxygen should now be applied to the system.

Care should be taken when setting the tarpaulin so as not to unduly reduce the volume of the treatment bath. If fish treatment densities are too high, scaling and hyperactivity may occur. A suggested maximum treatment density would be 150 kg/m^3 but this would be dependent on fish size, year class etc. Fish must not be fed for at least 24 hours prior to treatment.

If nets are heavily fouled, care should be taken when using hydrogen peroxide. Bottle weights should be applied around the periphery of the treatment bath to prevent flotation of the net. These should be applied before commencing the treatment.

The estimated volume of the product to produce the treatment concentration of approximately 1500 mg/L hydrogen peroxide should now be administered using safe and compatible dosing equipment.

To achieve an effective concentration of 1500 mg/L in a cage, approximately 2.6 litres of the product will be needed for every metre cube of water to be treated.

The following steps should be followed before treatment commences.

1. Assess the water volume to be treated in m^3.

2. Multiply the water volume by 2.55 to obtain the volume in litres of product required to achieve a concentration of 1500 mg/L hydrogen peroxide.

3. Add the product to the cage using the dedicated dosing equipment.

4. Once the addition is completed, a sample of the treated water should be taken and analysed immediately to obtain the confirmation of concentration in the cage.

Samples of water should be taken at several points to assess the concentration of the treatment solution using a suitable test method.

If the treatment concentration is found to be low, sufficient hydrogen peroxide should be added to achieve the treatment concentration.

The required volume of product to be added may be estimated from the following table:

a) Locate the concentration as measured on assay in the row across the top.

b) Proceed down this column to reach the row associated with the initial estimated volume.

c) The resulting figure gives the additional volume to be added to the pen.

Estimated water volume (m^3)	Volume of ASPERIX Vet to add (L)	Additional volume ASPERIX Vet to add in litre if reading is (mg/L)							
		700	800	900	1000	1100	1200	1300	1400
25	64	73	56	42	32	23	16	10	5
50	127	146	111	85	64	46	32	20	9
75	191	218	167	127	95	69	48	29	14
100	255	291	223	170	127	93	64	39	18
125	318	364	279	212	159	116	80	49	23
150	382	437	334	255	191	139	95	59	27
175	446	509	390	297	223	162	111	69	32
200	509	582	446	340	255	185	127	78	36
225	573	655	501	382	286	208	143	88	41
250	637	728	557	424	318	231	159	98	45
275	700	800	613	467	350	255	175	108	50
300	764	873	668	509	382	278	191	118	55
325	828	946	724	552	414	301	207	127	59
350	891	1019	780	594	446	324	223	137	64
375	955	1091	836	637	477	347	239	147	68
400	1019	1164	891	679	509	370	255	157	73
425	1082	1237	947	722	541	394	271	167	77
450	1146	1310	1003	764	573	417	286	176	82
475	1210	1382	1058	806	605	440	302	186	86
500	1273	1455	1114	849	637	463	318	196	91
750	1910	2183	1671	1273	955	694	477	294	136
1000	2546	2910	2228	1698	1273	926	637	392	182
2000	5093	5821	4456	3395	2546	1852	1273	784	364
3000	7639	8731	6684	5093	3820	2778	1910	1175	546
5000	12732	14551	11141	8488	6366	4630	3183	1959	909

If treatment concentration is high, the contact time may be reduced or the tarpaulin should be dropped. A contact time of between 15-20 minutes should prove sufficient for effective removal of lice.

9. ADVICE ON CORRECT ADMINISTRATION

Measurement of the concentration of hydrogen peroxide in solution should be continued during treatment and after the tarpaulin has been removed to ensure efficient dispersion has occurred.

During the treatment, fish must be observed for any signs of atypical behaviour. If fish appear distressed, e.g. losing equilibrium or becoming hyperactive during treatment, remove the tarpaulin and lower the net.

After treatment ensure that residual hydrogen peroxide is dispersed in the local vicinity as quickly as possible, perhaps using the wash of a boat propeller.

Commercially available test kits may be used to monitor low levels of residual hydrogen peroxide.

A second application may be required (dependent on routine lice monitoring), to ensure the removal of previous surviving chalami, which will have to moulted through to pre-adult stages. Care should be taken not to allow a build-up of mature lice as resettlement of copepodids could occur.

Where possible, treatments should be conducted during periods of high tidal flow to ensure good dispersal of residual hydrogen peroxide and dislodged lice. This will minimise any possible resettlement of lice.

10. WITHDRAWAL PERIOD

Meat: Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in the original container.
Do not return product to original container.
Store in a secure place and out of reach of children
Do not store above 25 °C.
Protect from direct sunlight.
Store away from heat sources.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special precautions for use in animals:

If problems occur when raising nets or setting the tarpaulin extending the time that fish are constricted within the treatment bath, extra care should be taken as fish may be unduly stressed prior to hydrogen peroxide addition.

In the event that fish begin to lose their equilibrium and possibly begin to sink during treatment with hydrogen peroxide, tarpaulins must be removed immediately. Residual hydrogen peroxide should be flushed from the cage using the wash from a boat.

Oxygen sparges should remain in the cage even if they are not used during treatment. This provides the ability to agitate moribund fish preventing them settling on the floor of the net. Affected fish should recover after a short period when nets may be dropped to their full extent.

If during treatment with hydrogen peroxide fish become hyperactive, this may be indicative of increased hydrogen peroxide concentrations or that fish have become unduly stressed.

Hydrogen peroxide concentration may be tested with a suitable test method and dissolved oxygen should be monitored to prevent an oxygen crash occurring. In the event that the hydrogen peroxide and dissolved oxygen concentration are normal but hyperactivity persists, treatment should be stopped. This should prevent a subsequent oxygen crash and minimise scaling of fish.

The nets should be partially lowered to increase the volume of water available to the fish and hydrogen peroxide residuals should be flushed away using the wash from a boat. These actions should relieve any undue stress to the fish.
The activity of the fish should be allowed to return to normal before the nets are completely dropped.

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

Harmful

Corrosive

Oxidising Agent

Do not attempt to administer the product unless you have been fully trained to handle and use the product, and are fully aware of operational and safety procedures. Hydrogen peroxide is corrosive.

This product is harmful if swallowed or if inhaled and may cause respiratory irritation. Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.

Avoid contact with skin and eyes. This product may cause skin irritation and serious eye damage.

Wear personal protective equipment whilst handling this product, consisting of chemically resistant headgear, face shield or safety goggles, chemically resistant PVC acid suit/ oilskins, chemically resistant PVC gloves (with cuff under suit) and safety rubber boots (with suit over boots).

Before commencing handling of this product ensure a supply of fresh water and preferably eye wash solutions are available.

IN CASE OF INHALATION: Remove person to fresh air and keep comfortable for breathing. If you feel unwell SEEK IMMEDIATE MEDICAL ATTENTION by calling a physician or National Poisons Information Centre.

IN CASE OF ACCIDENTAL EYE CONTACT: Rinse immediately with plenty of clean water for several minutes. SEEK IMMEDIATE MEDICAL ATTENTION by calling a

physician or National Poisons Information Centre. Remove any contact lenses, if easy to do so and continue rinsing eyes.

IN CASE OF ACCIDENTAL SKIN CONTACT: Immediately remove any contaminated clothing. Wash the exposed skin immediately with water and seek medical advice if irritation persists. Thoroughly clean the contaminated clothing by soaking with plenty of water before re-using.

IN CASE OF ACCIDENTAL INGESTION: Seek medical attention immediately and show the package leaflet or the label to the physician.

Always wash hands with soap and water directly after use.

Incompatibilities:
Keep away from acids, alkalis, reducing agents and metal salts.

Other precautions:
Depending on regional requirements, the user may need to apply for and obtain consent for discharge. Check with the relevant regional legislative body e.g. SEPA in Scotland.
The most important mechanisms for removal of hydrogen peroxide in coastal waters are dilution and degradation which are increased by water movements including the flushing effects in sea lochs. Do not use at times of slack water as poor dilution and dissociation of residuals may occur.
After treatment care should be taken to provide sufficient water through the net to dilute residual hydrogen peroxide. The water from a boat's propeller may be used to increase water exchange in cases where low water exchange rates cannot be avoided. These measures will help to prevent possible adverse effects on aquatic life.
Do not allow concentrated product to contaminate wood, paper, grass or any other combustible materials as this may cause fire.
A water hose or other plentiful water supply should be available to dilute any spills and leaks of the product.
Do not return any product to original container.
Use clean and vented containers to retain any spilled product.'

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

Harmful to aquatic life. Do not contaminate water courses or confined inlets with concentrated product as high concentrations may be deleterious to some marine species.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack size: 25 m^3 (25 000 litres) ISO-container. For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

United Kingdom
{Name}
<{Address}
{Town} {Postal code} – UK>
Tel: + {Telephone number}
<{E-mail}>

Norge
{Navn}
<{Adresse}
N-0000 {poststed}>
Tlf: + {Telefonnummer}
<{E-mail}>