

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 m³ (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)

Vm 33250/4000

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
45128 Essen
Germany

Manufacturer responsible for batch release:

Evonik Antwerpen N.V.
Tijlmanstunnel 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/m³ 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 m³.
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 moult 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 spargers 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 m³ (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}>

Approved 26 June 2020

