

<u>SUMMARY OF PRODUCTS CHARACTERISTICS</u>		
1.	NAME OF THE VETERINARY MEDICINAL PRODUCT	
	Paramove, 49.5% w/w Hydrogen Peroxide concentrate for solution for fish treatment.	
2.	QUALITATIVE AND QUANTITATIVE COMPOSITION	
	<u>Active Substance</u> 49.5% w/w Hydrogen Peroxide	<u>Excipients</u> Disodium dihydrogen diphosphate Nitric Acid Demineralised Water
3.	PHARMACEUTICAL FORM	
	Concentrate for solution for fish treatment. The product is a clear, colourless liquid.	
4.	CLINICAL PARTICULARS	
4.1	Target species	
	Atlantic Salmon	
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, <i>Lepeophtheirus salmonis</i> or <i>Caligus spp</i> , prior to the stage where serious tissue damage occurs.	
4.3	Contraindications	
	<p>Do not exceed the recommended concentration of hydrogen peroxide.</p> <p>Do not use at high water temperatures.</p> <p>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.</p> <p>Do not use in fish with a mean weight of less than 200g.</p> <p>Do not treat fish which are showing clinical signs of previous gill damage. If signs of atypical behaviour, e.g. fish losing equilibrium or hyperactivity are observed, treatment should be stopped immediately. An assessment of gill condition and the possibility of other stressors e.g. algal blooms should be</p>	

	made before commencement of treatments. Do not use in stressed fish.
4.4	Special warnings
	Repeated use of the same chemotherapeutic agent may encourage the development of resistance to the agent.
4.5	Special precautions for use
i.	Special precautions for use in animals
	<p>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.</p> <p>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.</p> <p>Oxygen sparges should remain in the cage even if they are not used during the 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.</p> <p>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.</p> <p>Hydrogen peroxide concentration may be tested using the Solvay 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.</p> <p>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.</p>
ii.	Special precautions for the person administering the veterinary medicinal product to animals



Xn HARMFUL

Oxidising Agent



Corrosive



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.

This product can cause skin, eye and respiratory irritation.

Avoid breathing in product fumes, and avoid contact with skin and eyes.

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 wellington boots (with suit over boots).

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

Wash hands after use.

In case of accidental exposure to the product, immediately soak all clothing with copious volumes of water, from a water supply, remove any contaminated clothing and thoroughly clean the contaminated clothing before re-using.

In case of accidental contact with eyes, rinse immediately with plenty of clean running water and seek medical advice.

After contact with skin, wash immediately with plenty of water.

	<p>In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).</p> <p>In case of accidental ingestion of the product, seek medical attention immediately showing the physician the product label.</p>
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iii	Other precautions
	<p>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.</p> <p>The most important mechanism 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 exchange through the net to dilute residual hydrogen peroxide. The wash 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.</p> <p>Do not allow concentrated product to contaminate wood, paper, grass or any other combustible materials as this may cause fire.</p> <p>A water hose or other plentiful water supply should be available to dilute any spills and leaks of the product.</p> <p>Do not return any product to original container.</p> <p>Use clean and vented containers to retain any spilled product.</p>
4.6	Adverse reactions (frequency and seriousness)
	<p>Adverse reactions with the product are rare.</p> <p>Any cellular damage to the gill during treatment is transient and reparable. See Section 4.3.</p> <p>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.</p> <p>Measures to treat fish undergoing adverse reactions are detailed in section 4.5.</p>
4.7	Use during pregnancy, lactation or lay
	Not applicable.
4.8	Interaction with other medicinal products and other forms of interaction
	<p>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.</p> <p>Where medicaments have been given and gill function may be compromised,</p>

	<p>hydrogen peroxide should not be administered.</p> <p>Refer to section 4.5 for further information.</p>
4.9	<p>Amount(s) to be administered and administration route</p> <p>For external use only.</p> <p>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.</p> <p>By total enclosure method at a concentration of approximately 1500 mg l⁻¹ as hydrogen peroxide for a maximum of 20 minutes contact.</p> <p>Infested fish should be bathed in 1500 mg l⁻¹ 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.</p> <p>The product is administered by the total enclosure method in which the fish cage net is raised to an approximate 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.</p> <p>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.</p> <p>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 treatment.</p> <p>The estimated volume of the product to produce the treatment concentration of approximately 1500 mg l⁻¹ hydrogen peroxide should now be administered using safe and compatible dosing equipment.</p> <p>To achieve an effective concentration of 1500 mg l⁻¹ in a cage, you will need approximately 2.6 litres of the product for every metre cube of water to be treated.</p> <p>The following steps should be followed before any treatment commences.</p> <ol style="list-style-type: none"> 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⁻¹ hydrogen peroxide.

3. Add the product to the cage using the dedicated dosing equipment and the volume scale on the IBC to measure the approximate volume.

4. Once the addition is complete, 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 the simple titration test method provided.

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

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

1. Locate the concentration as measured on assay in the row across the top.
2. Proceed down this column to reach the row associated with the initial estimated volume.
3. The resulting figure gives the additional volume to be added to the pen.

Estimated water volume (m ³)	Volume of Paramove to add (L)	Estimated water volume (m ³)	Additional volume Paramove to add in litres if reading is (mg/l ⁻¹)							
			700	800	900	1000	1100	1200	1300	1400
25	64	25	73	56	42	32	23	16	10	5
50	127	50	146	111	85	64	46	32	20	9
75	191	75	218	167	127	95	69	48	29	14
100	255	100	291	223	170	127	93	64	39	18
125	318	125	364	279	212	159	116	80	49	23
150	382	150	437	334	255	191	139	95	59	27
175	446	175	509	390	297	223	162	111	69	32
200	509	200	582	446	340	255	185	127	78	36
225	573	225	655	501	382	286	208	143	88	41
250	637	250	728	557	424	318	231	159	98	45
275	700	275	800	613	467	350	255	175	108	50
300	764	300	873	668	509	382	278	191	118	55
325	828	325	946	724	552	414	301	207	127	59
350	891	350	1019	780	594	446	324	223	137	64
375	955	375	1091	836	637	477	347	239	147	68
400	1019	400	1164	891	679	509	370	255	157	73
425	1082	425	1237	947	722	541	394	271	167	77
450	1146	450	1310	1003	764	573	417	286	176	82
475	1210	475	1382	1058	806	605	440	302	186	86
500	1273	500	1455	1114	849	637	463	318	196	91
750	1910	750	2183	1671	1273	955	694	477	294	136
1000	2546	1000	2910	2228	1698	1273	926	637	392	182
2000	5093	2000	5821	4456	3395	2546	1852	1273	784	364
3000	7639	3000	8731	6684	5093	3820	2778	1910	1175	546
5000	12732	5000	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

	<p>for effective removal of lice.</p> <p>Measurement of the concentration of hydrogen peroxide in solution should be continued during the treatment and after the tarpaulin has been removed to ensure efficient dispersion has occurred.</p> <p>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 the treatment, remove the tarpaulin and lower the net. Reference should be made to section 4.5.</p> <p>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.</p> <p>Merckoquant 110011 teststicks (Graduations: 0.5-2-5-10-25 mg/l) or Reflectoquant teststicks Merck 116974 (Range 0.2 – 20 mg/l) or similar commercially available test kits may be used to monitor low levels of residual hydrogen peroxide.</p> <p>Methods of analysis, advice on test kits, dosing equipment and product handling, and Safety Data Sheets for the product are available from the supplier.</p> <p>A second application may be required (dependent on routine lice monitoring), to ensure the removal of previously surviving chalami, 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.</p> <p>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.</p>
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4.10	Overdose (symptoms, emergency procedures, antidotes), if necessary
	<p>An overdose situation may occur by two methods:</p> <ul style="list-style-type: none"> i) Addition of too much hydrogen peroxide to the treatment bath producing a higher concentration than recommended. <p>In this event refer to contraindications and warnings.</p> <ul style="list-style-type: none"> ii) 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. <p>Strong solutions of hydrogen peroxide produce irritation and 'burning' of skin and mucous membranes or gills.</p> <p>Emergency procedures: remove tarpaulins immediately and flush hydrogen peroxide from the cage using the wash from a boat.</p>
4.11	Withdrawal period(s)
	Meat: zero days
5.	PHARMACOLOGICAL PROPERTIES
	Pharmacotherapeutic group:
	Dermatological; antiseptics and disinfectants
	ATC Vet Code:
	QD08AX01
5.1	Pharmacodynamic properties
	<p>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 to of the hydrogen peroxide in to oxygen and water may cause temporary or permanent disruption to internal structures, causing the parasite to detach from the host.</p> <p>Resistance to hydrogen peroxide has been reported on one farm after fish were treated with hydrogen peroxide regularly (41 treatments) over a 6 year period. The proposed mechanisms of resistance were genetic selection of individuals with a cuticle that provides a barrier to penetration by hydrogen peroxide or the presence of detoxifying enzymes.</p>

5.2	Pharmacokinetic properties
	<p>Absorption</p> <p>As hydrogen peroxide is administered typically as a 20 minute bath treatment, absorption by the host is considered to be negligible.</p> <p>Distribution</p> <p>Not applicable.</p> <p>Biotransformation</p> <p>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.</p> <p>Elimination</p> <p>As above, break down of any hydrogen peroxide residual would be enzymic. Excretion of hydrogen peroxide would not occur.</p>
5.3	Environmental properties
6.	PHARMACEUTICAL PARTICULARS
6.1	List of excipients
	<p>Disodium dihydrogen diphosphate ($\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$)</p> <p>Nitric acid ($\text{HNO}_3$)</p> <p>Demineralised Water</p>
6.2	Incompatibilities
	Keep away from acids, alkalis, reducing agents and metal salts.
6.3	Shelf life
	10 months

6.4	Special precautions for storage
	<p>Store in closed original container.</p> <p>Do not return product to original container.</p> <p>Store in a secure place and out of reach of children</p> <p>Do not store above 25°C. Protect from direct sunlight. Store away from heat sources.</p> <p>Do not store containers on rafts at sea.</p>
6.5	Nature and composition of immediate packaging
	<p>Single use Intermediate Bulk Containers (IBCs) of 1100 Kg.</p> <p>Reusable stainless steel ISO-containers of 22,900 Kg.</p>
6.6	Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate
	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 products should be disposed of in accordance with local requirements.
7	MARKETING AUTHORISATION HOLDER
	<p>Solvay Chemicals International S. A.</p> <p>Rue de Ransbeek 310</p> <p>B-1120 Brussels</p> <p>Belgium</p>
8.	MARKETING AUTHORISATION NUMBER(S)
	<p>UK Vm 31011/4000</p> <p>Ireland VPA 10480/001/001</p> <p>Norway Vnr 11-8486</p>
9.	DATE OF FIRST AUTHORISATION
	Date: TBC
10.	DATE OF REVISION OF THE TEXT
	Date: TBC

	Prohibition of sale, supply and/or use:
	None