

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Paramove 49.5% w/w Hydrogen Peroxide concentrate for solution for fish treatment

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

49.5%w/w Hydrogen Peroxide

3. PHARMACEUTICAL FORM

Concentrate for solution for fish treatment

4. PACKAGE SIZE

Single use Intermediate Bulk Containers IBCs of 1,100 kg
Reusable stainless steel ISO-container of 22,900 kg
Reusable stainless steel ISO-container of 26,000 kg

5. TARGET SPECIES

Atlantic Salmon

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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/l¹ as hydrogen peroxide for a maximum of 20 minutes contact.

Infested fish should be bathed in 1500 mg/l¹ 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 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.

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 kgm^{-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 treatment.

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.

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.

The following steps should be followed before any 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^{-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.

Table 1

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 for effective removal of lice.

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.

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.

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.

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.

Methods of analysis, advice on test kits, dosing equipment and product handling, and Safety Data Sheets for the product are available from the supplier.

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.

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.

Marketing Authorisation Holder	Solvay Chemical International S.A, Rue de Ransbeek 310, B-1120 Brussels, Belgium
Marketing Authorisation Numbers	Ireland VPA 10480/001/001 POM (included on English language label) Norway11-8486 (included on Norwegian language label) United Kingdom Vm 31011/4000 POM-V (included on English language label)
Manufacturer	SOLVAY INTEROX LTD Warrington, England WA4 6HA Tel: +44 (0)1925 651277 SOLVAY CHIMIE S.A. Jemeppe-sur-Sambre 5190 Belgium Tel: +32 (0)71 268 111 SOLVAY CHIMIE N.V. ZANDVLIET Schedelaan 600, Haven 725 B-2040 Antwerpen (Anvers) Belgium Tel: +32 (0)35 615 432
Distributor/ Wholesaler	Aqua Pharma Ltd Seafield House 2 Seafield Road Inverness, IV1 1SG Tel: +44(0) 1463 233361 Fax: +44(0) 1463 718735 (included on English language label only)

8. WITHDRAWAL PERIOD

Withdrawal period: (meat): zero days

9. SPECIAL WARNING(S), IF NECESSARY

User Warnings (as a VMP)

Do not attempt to administer the product unless you 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 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.

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 present and 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.

Always wash hands with soap and water directly after use.

User Warnings (classification under CLP)



DANGER
Oxidising Agent



Corrosive



Do not attempt to administer the product unless you are fully aware of operational and safety procedures.

Harmful if swallowed or if inhaled. This product causes skin irritation, serious eye damage, and may cause respiratory irritation.

Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.

Wear protective gloves / eye protection / face protection.

IF INHALED : Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER / doctor if you feel unwell.

IF IN EYES : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.

Store in a secure place.

Other Precautions

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

Do not use at times of slack water as poor dilution and dissociation of residuals may occur. The wash from a boat's propeller may be used to increase water exchange where low water exchange rates cannot be avoided.

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.

10. EXPIRY DATE

EXP: DD/MM/YYYY

11. SPECIAL STORAGE CONDITIONS

Store in closed original container.

Do not return any product to original container.

Do not store above 25°C. Protect from direct sunlight.

Store in a well-ventilated place. Keep container tightly closed. Store away from heat sources. Do not store containers on rafts at sea.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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 medical products should be disposed of in accordance with local requirements.

Dispose of contents/ container to an approved waste disposal plant.

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.

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.

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

Do not treat fish which are showing clinical signs of gill damage.

Do not use in stressed fish.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Solvay Chemicals International S.A.
Rue du Ransbeek 310
B-1120 Brussels
Belgium

16. MARKETING AUTHORISATION NUMBER

Vm 31011/5000

17. MANUFACTURER'S BATCH NUMBER

Batch {Number}

Available pack sizes:

Single use Intermediate Bulk Containers IBCs of 1,100 kg

Reusable stainless steel ISO-container of 22,900 kg

Reusable stainless steel ISO-container of 26,000 kg

Not all pack sizes may be marketed.

Approved: 08 November 2017

