Veterinary Medicines Directorate

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Veterinary Medicines Directorate
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DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Salmosan Vet, Azamethiphos 50% w/w Powder for Suspension for Fish Treatment

Date Created: February 2015

PuAR correct as of 07/11/2018 when RMS was transferred to NO.
Please contact the RMS for future updates

MODULE 1

PRODUCT SUMMARY

EU Procedure number	UK/V/0528/001/DC
Name, strength and pharmaceutical form	Salmosan Vet, Azamethiphos 50% w/w Powder for Suspension for Fish Treatment
Applicant	FVG (Fish Vet Group) Limited 22 Carsegate Road Inverness IV3 8EX Scotland
Active substance	Azamethiphos
ATC Vetcode	QP53AF17
Target species	Farmed Atlantic salmon (*Salmo salar*)
Indication for use	For treatment of pre-adult to adult sea-lice (*Lepeophtheirus salmonis* or *Caligus* species) on farmed Atlantic salmon.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Veterinary Medicines Directorate website (www.vmd.defra.gov.uk)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic 'hybrid' application in accordance with Article 13 (3) of Directive 2001/82/EC as amended.
Date of completion of the original decentralised procedure	19th November 2014.
Date product first authorised in the Reference Member State (MRP only)	Not applicable.
Concerned Member States for original procedure	Norway

I. SCIENTIFIC OVERVIEW

This application was for a generic 'hybrid' product, submitted in accordance with Article 13 (3) of Directive 2001/82/EC as amended. The reference product was Salmosan 50% w/w Powder for Suspension for Fish Treatment, (marketed by the applicant), and authorised in the UK since December 1996. The proposed product differs to the reference product in the excipient naphthalene sulphonic acid formaldehyde condensate, present in the reference product at 2% w/w has been removed.

The product is indicated for use in farmed Atlantic salmon, to treat pre-adult to adult sea-lice (*Lepeophtheirus salmons* or Caligus species) on farmed Atlantic salmon. Affected fish should be bathed in 0.2 ppm product (0.1 ppm azamehtiphos), for 30-60 minutes. 0.2 g of product is added per cubic metre of water.

The product is produced and controlled using validated methods and tests which ensure the consistency of the product released onto the market. It has been shown that the product can be safely used in the target species, any reactions observed are indicated in the SPC.[1] The product is safe for the user, the consumer of foodstuffs from treated animals and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC. The efficacy [2] of the product was demonstrated according to the claims made in the SPC. The overall benefit/risk analysis is in favour of granting a marketing authorisation.

[1] SPC – Summary of product Characteristics.
[2] Efficacy – The production of a desired or intended result.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTIUENTS

II.A. Composition

The product contains azamethiphos at 500 mg/g and the excipients sodium lauryl sulphate, kaolin light and silicic acid precipitated. The container/closure system consists of heat-sealed PVA water soluble bag containing 20 g or 100 g of product contained in a sealed polyethylene lined paper sachet. There are 5 x 20g or 2 x 100g packages in a box. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and absence of preservative are justified. The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. Process validation data on the reference product were provided, with process validation to be provided post-authorisation on the proposed product. Validation was performed on three batches of 50 kg of product. The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site. Process validation data on the product have been presented in accordance with the relevant European guidelines. The manufacturing process is a simple solubilisation process, with active substance and excipients being mixed as appropriate. In-process analyses are performed at various time points, before the product is filled into containers.

II.C. Control of Starting Materials

The active substance is azamethiphos, an established active substance which is not described in the European Pharmacopoeia (Ph. Eur). Instead the applicant provided a suitable specification. The active substance is manufactured in accordance with the principles of good manufacturing practice. The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided. The excipient monographed in the Ph. Eur is sodium lauryl sulphate. Light kaolin is cited in the British Pharmacopoeia, and a suitable specification was provided for silicic acid.

II.C.4. Substances of Biological Origin

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product. Satisfactory validation data for the analytical methods have been provided. Batch analytical data from the proposed production site have been provided demonstrating compliance with the specification. Tests on the finished product include those for appearance, identity, pH, suspensibility, wettability, wet sieve residue, moisture, bag content and disintegration of bag.

II.F. Stability

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions. Data for three 250 kg production lots of the active substance were tested at VICH[3] conditions, (25°C/60% RH and 40°C/75% RH). Testing periods were 3 and 6 months for accelerated conditions and 3, 6, 9, 12, 18 and 24 months for real time analyses. All aspects of storage were considered satisfactory. A retest period of 36 months was agreed.

For the finished product, samples from a variety of batches were tested under VICH conditions, (25°C/60% RH and 40°C/75% RH) in commercial containers, and for a variety of time periods ranging from 1.5 to 6 months for the accelerated conditions and 18 months and 24 months for real time conditions. Results were satisfactory, with the SPC reflecting storage precautions required to maintain the product at optimum efficacy.

G. Other Information

Shelf-life of the veterinary medicinal product as packaged for sale.
3 years.
Do not store above 25ºC.
Store in the original unopened packaging.
Store in a dry place.
Store away from food, drink and animal feedingstuff.

[3] VICH – International Cooperation in Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

This was an application for a generic 'hybrid product, according to Article 13 (3) of Directive 2001/82/EC, as amended. The applicant did not provide pharmacological or toxicological data, which was acceptable, referring instead to data provided for the reference product.

Warnings and precautions as listed on the product literature are the same as those of the reference product and are adequate to ensure safety of the product to users, the environment and consumers.

III.A Safety Documentation

User Safety

A fully comprehensive user risk assessment was provided in compliance with the relevant guideline, which discussed the characterisation of risk, risk management and communication of risk to the appropriate users. Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product:

This product contains azamethiphos. Azamethiphos is an organophosphorus compound. DO NOT USE if under medical advice not to work with such compounds.

THIS PRODUCT MAY CAUSE SENSITISATION (ALLERGY) BY SKIN CONTACT OR INHALATION.

AVOID ALL CONTACT WITH MOUTH, SKIN OR EYES.

ACCIDENTAL SPLASHES ON EXPOSED SKIN OR EYES should be washed off immediately with plenty of water.

WEAR SUITABLE PROTECTIVE CLOTHING SUCH AS WATERPROOF COVERALLS, HEAVY DUTY GAUNTLET STYLE NITRILE GLOVES of at least 300 mm length and 0.5 mm thickness, FACE SHIELD AND RESPIRATORY PROTECTION, both when handling the concentrate and when applying the diluted chemical to the pen.

RENEW PROTECTIVE CLOTHING AND EQUIPMENT REGULARLY and certainly when cracking or damage has occurred.

WASH ALL PROTECTIVE CLOTHING thoroughly after use, especially the insides of gloves.

REMOVE HEAVILY CONTAMINATED CLOTHING IMMEDIATELY after a spill; wash or destroy.

Ensure that the drum/container is securely closed during the dissolving process.

DO NOT EAT, DRINK OR SMOKE without first withdrawing from the work area, removing protective clothing and washing hands, face and exposed skin.

WASH HANDS, FACE AND ANY EXPOSED SKIN immediately after leaving the work area.

KEEP AWAY FROM FOOD, DRINK AND ANIMAL FEEDINGSTUFFS.

RINSE APPLICATION EQUIPMENT AND CONTAINERS AFTER USE.

MEDICAL ADVICE TO USERS

- If you have previously felt unwell after using a product containing an organophosphorus compound, consult your doctor before working with this product and show your doctor the product label.
- If you feel unwell after using this product, consult your doctor and show your doctor the product label.
- Treat any cases of heavy contamination as an emergency. You should go straight to hospital after removing contaminated clothing, and rinse areas of skin which came into contact with the product with plenty of water.
- If the product has been swallowed go straight to hospital and take the product label with you.

MEDICAL ADVICE TO DOCTORS

Poisoning from organophosphorus compounds results from blockage of acetylcholinesterase, with a resulting over-activity of acetylcholine.

Symptoms include headache, exhaustion and weakness, mental confusion together with blurred vision, excessive salivation and sweating, cramp-like abdominal pain, chest tightness, diarrhoea, constricted pupils and bronchorrhea. These may develop for up to 24 hours after exposure.

Severe poisoning can include general muscle twitching, loss of coordination, extreme difficulty with breathing and convulsions which may lead to unconsciousness in the absence of medical treatment. Treat symptomatically and seek urgent hospital transfer if poisoning is suspected.

Advice on clinical management is available from the National Poisons Information Service.

REPORTING INCIDENTS

In the UK:

Illness suspected to be a result of working with this product may be reportable under the Reporting of Injuries, Diseases and Dangerous Occurrences

Regulations 1985. If in doubt contact your local Health and Safety Executive Officer.

Report suspected adverse reactions to the Fish Vet Group, 22 Carsegate Road, Inverness, IV3 8EX, Scotland. Tel: +44 (0) 1463 717774, 24 hour emergency number 0845 0093342, or directly to the Veterinary Medicines Directorate online at http://www.vmd.defra.gov.uk/adversereactionreporting/

In Norway:

Adverse reactions, including human reactions, should be reported to the Norwegian Medicines Agency, www.noma.no.

Further advice can be obtained from: Fish Vet Group, 22 Carsegate Road, Inverness, IV3 8EX, Scotland. Tel: +44 (0) 1463 717774. info@fishvetgroup.com

Environmental Safety

An Environmental Risk Assessment (ERA) was conducted in accordance with VICH and CVMP guidelines.

Phase I:
The product is a powder for dilution in water containing the active substance azamethiphos (50 % w/w). Due to the use of the product there is the potential for azamethiphos to be released into the environment. Exposure will be via the water containing azamethiphos, used to treat farmed Atlantic salmon, being discharged into the marine environment.

A Phase I environmental risk assessmentwas provided which showed that a Phase II assessment was required as the product is an endoparasiticide to be used in a non-confined aquatic environment (as stipulated, VICH decision tree).

Phase II Tier A:
A Phase II Tier A data set was provided according to the requirements of the VICH GL 38 and the CVMP guideline in support of the VICH guidelines, including studies on physico-chemical properties, environmental fate and effects. Studies were carried out using the active substance unless indicated otherwise.

Physico-chemical properties

Study type	Guideline	Result	Remarks

Study type	Guideline	Result	Remarks
Water solubility	OECD 105	1.60 g/l (pH 5.0) 1.27 g/l (pH 7.0) 0.881 g/l (pH 9.0)	flask method
Dissociation constants pKb	OECD 112	PKb 12.9	
UV-Visible Absorption Spectrum	OECD 101	Neutral test solution: • 295 nm = 1.02 x 10^4 (l/mol/cm) • 231 nm = 0.914 x 10^4 (l/mol/cm) Acid test solution: • 294 nm = 1.02 x 10^4 (l/mol/cm) • 230 nm = 0.929 x 10^4 (l/mol/cm) Basic test solution: • 316 nm = 0.828 x 10^4 (l/mol/cm) 251 nm = 0.729 x 10^4 (l/mol/cm)	Characteristic spectrum obtained
Melting temperature	OECD 102	90°C (363K)	
n-Octanol/Water Partition Coefficient $logP_{ow}$	OECD 107	Log Pow = 1.0	Indicates low affinity for sorption to organic matter

Environmental fate

Study type	Guideline	Result	Remarks
Soil/sewage sludge Adsorption coefficient	OECD 121	K_{oc} 99 l/kg (pH 5.5 to 7.5)	Indicates moderate mobility of azamethiphos in soil/sewage sludge
Biodegradation - Aerobic mineralisation in Surface Water	OECD 309	DT_{50} of 8.9 days	Not persistent

Environmental effects

The findings of the provided toxicity studies, conducted in 26 aquatic species, are summarised as follows:

Group	Species (life stage)	Toxicity endpoint	Concentration (µg/l)
Fish	*Gasterosteus aculeatus* (juvenile)	24 (h) LC_{50}[4]	not given
		48 (h) LC_{50}	not given
		72 (h) LC_{50}	not given
		96 (h) LC_{50}	190
	Odonthestes regis (juvenile)	24 (h) LC_{50}	4233
		48 (h) LC_{50}	1700
		72 (h) LC_{50}	213.9
		96 (h) LC_{50}	29.38
	Ctenolabrus rupestris (juvenile)	1 (h) LC_{50}	3350
			4140
			4180
	Clupea harengus (Yolk-sac)	96 (h) LC_{50}	33.4
	Clupea harengus (Post Yolk-sac)		
Algae	*Phaeodactylum tricornutum*	72 (h) NOEC[5]	1000
	Isochrysis galbana	24 (h) LC_{50}	1533
		48 (h) LC_{50}	2099
		72 (h) LC_{50}	2348
		96 (h) LC_{50}	3066
	Tetraselmis chuii	15 (h) NOEC	1000
Invertebrates	Rotifer: *Brachionus plicatilis*	24-96 (h) LC_{50}	>10000
	Polychaete: *P. comuta* (Juvenile)	96 (h) LC_{50}	2310
	Sea urchin: *S. droebachiensis* (adult)	96 (h) LC_{50}	>1000
	Painted sea urchin: *Lytechinus pictus*	0.3 (h) LC_{50}	>6840
	Sea urchin: *Loxechinus albus (adult)*	48 (h) LC_{50}	>456
	Starfish: *Asterias rubens*	96 (h) EC_{50}[6]	14
		96 (h) LC_{50}	>100
	Giant oyster: C. *gigas* (embryo)	24 (h) NOEC	1000
	Periwinkle: *L. littorea* (adult)	24 (h) EC_{50}	1.6
		96 (h) EC_{50}	2.6
		24 (h) NOEC	25
		96 (h) NOEC	1.5
	Edible blue mussel: *M. edulis* (adult)	1 (h) LC_{50}	736
		24 (h) LC_{50}	>10000
		24 (h) EC_{50}	29
		96 (h) NOEC	1.5

[4] LC_{50} – The concentration that kills half a sample population
[5] NOEC – No observable effect concentration
[6] EC_{50} – Half the maximal effective concentration

Group	Species (life stage)	Toxicity endpoint	Concentration (µg/l)
	Edible blue mussel: *M. edulis* (adult)	24 (h) LC_{50}	46
		24 (h) EC_{50}	91
		96 (h) NOEC	10
	Edible blue mussel: *M. edulis* (adult)	1 (h) LC_{50}	>10<100
	Limpet: *P. vulgaris* (adult)	24 (h) EC_{50}	6.9
		96 (h) EC_{50}	0.76
	Copepod: *Temora longicornis*	24 (h) LC_{50}	>10
	Freshwater shrimp: *Gammarus* spp.	96 (h) LC_{50}	<5
	Brine shrimp: *Artemia salina*	24 (h) LC_{50}	>10000
	King crab: *Lithodes santolla* (larvae)	48 (h) LC_{50}	9.12
		72 (h) IC_{50}	0.89
	Amphipod: *Hyale prevostii*	24 (h) EC_{50}	2.4
		96 (h) EC_{50}	0.82
	Amphipod: *Eohaustaurius estauris*	48 (h) EC_{50}	2.6
		48 (h) LC_{50}	20
		96 (h) LC_{50}	20
	Mud shrimp: *Corophium volutator'*	240 (h) LC_{50}	182
	Shrimp: *Mysidopsis bahia*	96 (h) LC_{50}	0.52
	European lobster: *Homarus gammarus* (Stage IV larvae)	24 (h) EC_{50}	0.36
		48 (h) LC_{50}	1.25
		96 (h) LC_{50}	0.52

PECs[7] for surface water have been calculated according to the SEPA[8] manual for models as recommended by the CVMP guidance document, EMEA/CVMP/ERA/418282/2005-Rev.1 (page 36/65 Section 4 *Aquaculture branch*). The environmental impact of using azamethiphos was assessed using both the short term and the long term bath treatment models implemented by SEPA (SEPA, 2008) and the RQ[9] (PEC/PNEC[10]) for each of the aquatic trophic levels (marine fish, marine algae and marine invertebrates) were determined.

The applicant used the diffusion coefficient derivation in the model, as it represents the use of azamethiphos in the actual environment. The applicant reported the Tier A and B $PEC_{surface\ water}$ values as equivalent to the EQS values set in SEPA's short and long term models. In particular, 3 h after any discharge: EQS = 250 ng/l; 72 h after final discharge: EQS = 40 ng/l. This approach was deemed acceptable as it represents a reasonable worst case (i.e. the EQS values are equivalent to the highest $PEC_{surface\ water}$ allowed based on the SEPA short and long term models). The applicant compared the EQS values to

[7] PEC – Predicted Environmental Concentration
[8] SEPA – Scottish Environmental Protection Agency
[9] RQ – Risk Quotient
[10] PNEC – Predicted No Effect Concentration

appropriate acute and chronic effect endpoints with suitable assessment factors. It was determined that further evaluation of the risk to fish and marine invertebrates was required for the exposure scenarios that produced RQ values >1. As a result, the applicant refined the $PEC_{surface\ water}$ based on the SEPA long-term model which incorporated the 8.9 day DT_{50} degradation value. The model was run multiple times using the example selection of fish farm sites' characteristics, which were compared against the 72hr EQS and the 72hr MAC. The long term model demonstrated PECs of azamethiphos that would not breach the PNECs set by SEPA, i.e. RQ values less than 1. Due to the nature of the product, the risk to the environment is greatest immediately after treatment (RQ >1) but that this will reduce over time. It was concluded that the risk to aquatic organisms is acceptable providing the following environmental warnings are included on the SPC (section 4.5.iii "Other precautions") and product literature:

- The product is very dangerous to crustaceans and is dangerous to fish and other aquatic organisms; therefore the product should not be used in sea farms where crabs and lobsters are kept in close proximity of the treated cages.
- Frequent use and/or use on a larger scale may pose an increased risk to the environment. In order to ensure safe use (including large scale and multiple treatments) of the product under a combination of different environmental conditions (e.g. low water current speeds, shallow waters, short distance to the shore etc.), local environmental regulations governing discharges, where applicable, must be adhered to. **If there is any doubt about safe use, relevant competent authorities should be consulted or professional advice sought accordingly.**
- The most important mechanism for removal of the product in coastal waters is dilution which is increased by water movements including the flushing effects in sea lochs. After treatment, care should be taken to provide sufficient water exchange through the net to dilute residual azamethiphos. The water movements 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.
- From a practical use position, 'restrictive tarpaulins' are commonly available now and can be used to reduce the volume of larger net pens for bath treatments. Depending on biomass, these tarpaulins can reduce the size of larger pen nets by >60%. This is good practice which not only allows for better measurement of the water volume to be treated but also reduces the amount of product needed to be used and therefore released at the end of treatment.
- For countries where an environmental authorisation is not required at each individual site, the following risk mitigation measures should be followed:
    - At sites with cages ≥ 150 m in circumference, a maximum of one cage should be treated per day.
    - At sites with cages 120-149 m in circumference, a maximum of two cages should be treated per day.

In addition, the following information appears under Section 5.3 “Environmental properties” of the SPC:

- Azamethiphos is highly soluble in water (>1g/l) with a low octanol/water partition coefficient (log K_{ow}) of 1.0 g/ml. These characteristics indicate that azamethiphos will remain in the aqueous phase and will not enter the sediments. Azamethiphos has a moderate propensity to adsorb to suspended organic matter; however it is unstable in salt water, degrading with a half-life of <8.9 days (at 12°C), producing non-toxic transformation products. Hydrolytic degradation is the primary breakdown route but photolysis and microbial action will also hasten the process.

III.B.2 Residues documentation

Residue Studies

No residue depletion studies were conducted because Data were provided in relation to the reference product, and this was deemed acceptable. It was agreed that a 10 degree day withdrawal period was appropriate.

MRLs

The applicant provided maximum residue limit (MRL) data originally provided for the reference product, which showed that MRLs are not required for use in salmonidae species:

Ingredients	Marker residue	Animal species	MRLs (µg/kg)	Target tissues	Other provisions
Azamethiphos	None	Salmonidae	No MRL required	All	None
Sodium Lauryl Sulphate	None	All	No MRL required	All	None
Kaolin	None	All	No MRL required	All	None
Silicic acid			Out of scope		

Withdrawal Periods

Based on the data provided, a withdrawal period of 10 degree days was justified for use of the product in Atlantic salmon.

IV CLINICAL DOCUMENTATION

This is a generic ‘hybrid’ application according to Article 13 (3). The applicant was required to submit dissolution studies, in order that parity between the proposed product and the reference product could be confirmed.

IV.I. Pre-Clinical Studies

Pharmacology

The applicant conducted dissolution studies to show the similarity of the formulations of the proposed product and the reference product. Two replicates for each formulation, with azamethiphos at 0.1 ppm (equivalent to 0.2 ppm product) were performed. An initial study was carried out in aerated tanks containing no fish, and a second study was performed in field conditions. For all analyses, statistical data demonstrated that there was no significant difference between the proposed product and the reference product, and that therefore, essential similarity between the products was confirmed.

Tolerance in the Target Species

The applicant conducted a controlled target animal tolerance study using multiples of the recommended dose and two different water temperatures in the target species. All doses were administered as described in the SPC. The study was performed in order to evaluate the safety of the proposed product. Salmon were divided into 14 tanks. Two treatments were administered to fish with an interval of 10 days between treatments. The treatments were as follows:

	Number of animals			Amount of IVP* administered	Water temperature
	No of fish per tank	No of replicates	Total no of fish per group		
Group 1	11	2	22	0.055 g (1 x RTD)	6 ± 1°C
Group 2	11	2	22	0.109 g (2 x RTD)	6 ± 1°C
Group 3	11	2	22	0.163 g (3 x RTD)	6 ± 1°C
Group 4	11	2	22	0.055 g (1 x RTD)	15 ± 1°C
Group 5	11	2	22	0.109 g (2 x RTD)	15 ± 1°C
Group 6	11	2	22	0.163 g (3 x RTD)	15 ± 1°C
Group 7	11	1	11	0 g (control)	6 ± 1°C
Group 8	11	1	11	0 g (control)	15 ± 1°C

No significant events were noted in salmon given 3 x the recommended dose, at both 6°C and 15°C for a minimum of 180 minutes. The product literature accurately reflects any type and incidence of adverse effects which might be expected.

Resistance

The applicant provided suitable product literature in order to evaluate any incidences of resistance associated with the use of azamethiphos. Limited data are available on resistance to this active substance. Adequate warnings and precautions appear on the product literature.

IV.II. Clinical Documentation

As essential similarity with a reference product was established, there was not requirement for data in this section.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the benefit/risk profile of the product(s) is favourable

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MODULE 4

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)