

IRISH MEDICINES BOARD ACT 1995

ANIMAL REMEDIES REGULATIONS, 2005

(S.I. No. 734 of 2005)

VPA: **10934/001/001**

Case No: 7001946

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies Regulations (S.I. No. 734 of 2005) hereby grants to:

Abbott Laboratories Limited

Regulatory Affairs Manager,, Queensborough, ME11 5EL, England

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Sarafin 100 %w/w Premix for Med.Feedstuffs

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Sarafin 100% w/w Premix for medicated feed.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Sarafloxacin hydrochloride*	100%
(equivalent to Sarafloxacin base)	82%)

* Contains 10% water.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Premix for medicated feed.

4 CLINICAL PARTICULARS

4.1 Target Species

Atlantic Salmon.

4.2 Indications for use, specifying the target species

For the treatment and control of furunculosis in Atlantic salmon (*Salmo salar*) in sea water caused by *Aeromonas salmonicida* strains susceptible to sarafloxacin hydrochloride.

4.3 Contraindications

None

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Do not mix Sarafin in feed containing other therapeutic agents or growth promoters.

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

When mixing Sarafin in feed, goggles, impervious gloves and dust mask should be worn to avoid direct contact with the skin and inhalation of dust.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Not applicable.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For administration in fish feed at the rate of 10 mg per kg of bodyweight of fish per day. A five day course of treatment is recommended.

Sarafin may be incorporated in pelleted feed or mixed with feed just prior to dosing. The following inclusion rates for different feed rates will provide the recommended dose:

<u>DAILY FEEDING RATE</u>	<u>RATE OF INCLUSION OF SARAFIN</u>	
	Per 25 kg of feed	Per tonne of feed
% bodyweight		
0.5	50.0 g	2.0 kg
1.0	25.0 g	1.0 kg
2.0	12.5 g	0.5 kg

Since feeding rates may vary according to water temperature and size of fish, it may be convenient to medicate at a fixed rate, e.g. 1% bodyweight (25g Sarafin per 25 kg of feed or 1 kg Sarafin per tonne of feed) and meet any extra feeding requirement by providing unmedicated feed.

When mixing Sarafin with ready manufactured feed pellets, use the above table as a guide to quantities and ensure adequate mixing by using the following procedure: prepare a suspension of the Sarafin in edible oil (up to 1 litre per 25 kg of feed). Place one-quarter of the feed in the mixer, add the Sarafin-oil suspension and mix for 5 minutes. Add the remaining three-quarters of the feed and mix for a further 15 minutes until the Sarafin-oil suspension evenly coats the feed pellets.

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

Not applicable.

4.11 Withdrawal Period(s)

Fish intended for human consumption must not be slaughtered during treatment or within 150 degree days (e.g. 10 days at 15°C or 30 days at 5°C) after the end of treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Sarafin (sarafloxacin hydrochloride) is an arylfluoroquinolone antibacterial agent with a broad spectrum of activity. It shows high bactericidal activity against common aquaculture pathogens including *Aeromonas salmonicida*, the causative agent of furunculosis in Atlantic salmon (*Salmo salar*).

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

None known.

6.3 Shelf-life

Sarafin: 2 years

Sarafin medicated feed: 6 months

6.4 Special precautions for storage

Store in a dry place

Protect from direct sunlight

Re-seal container after use

Do not store on-farm mixed medicated feed

6.5 Nature and composition of immediate packaging

White opaque high density polypropylene bucket fitted with white opaque high density polypropylene lid, and lined with clear low density polyethylene liner sealed with a twist tie: contents 1 kg Sarafin.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Abbott Laboratories Ltd.,
Queenborough,
Kent,
ME11 5EL,
England

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10934/1/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23 January 2003