ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AQUACEN FORMALDEHIDO 380 mg/ml (ES)
AQUACEN FORMALDEÍDO 380 mg/ml (PT)
AQUACEN FORMALDEHYDE 380 mg/ml (EL)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
Formaldehyde.....380 mg

Excipients, q.s. .....1 ml

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Concentrate for dip solution.
Clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Target species

Fish: Turbot (*Psetta maxima*)
Gilthead (*Sparus aurata*)

4.2 Indications for use, specifying target species

Fish:
Turbot. Control of external parasitosis by *Philasterides dicentrarchi.* At the recommended dose and posology, the mortality of infested animals is reduced, but the infestation is not completely eliminated. The treatment is not effective once the parasite has penetrated inside the fish.
Gilthead. Treatment and control of external parasitosis by *Sparicotyle chrysophrii.*

4.3 Contraindications

Do not apply the medicinal product in water at temperature higher than 27ºC or when high concentrations of phytoplankton exist or when the oxygen concentration is less than 5 mg/litre, as the product may kill the phytoplankton and cause a depletion of dissolved oxygen. If oxygen depletion occurs, new well-aerated water should be added to dilute the solution and provide oxygen.
Do not use the medicinal product if it has been subject to temperatures below 5ºC or freezing, as cold causes the formation of paraformaldehyde which is a toxic substance for fish. Paraformaldehyde can be recognized as it is seen as a white precipitate at the bottom or on the walls of the container.

4.4 Special warnings for each target species

Fish with very high levels of parasite infection or sick fish may present a lower tolerance to treatment.

Tolerance to formaldehyde may vary with different batches or species of fish. Whenever possible, testing on a small number of fish is recommended to detect any case of sensitivity before applying the medicinal product.

4.5 Special precautions for use

Special precautions for use in animals

Fish with very high levels of parasite infection or sick fish may present a lower tolerance to treatment. The fish should be observed during treatment in case signs of stress appear, in which case the treated water should be discarded and replaced with non-treated and well-oxygenated water.

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

Handle the medicinal product with care to prevent contact while it is being added to the water, and during administration to the animals, taking specific precautions:

- Do not handle the medicinal product if hypersensitive to formaldehyde.
- Use gloves, work overall, approved mask and safety goggles.
- Avoid contact with skin and eyes. In case of contact, rinse abundantly with clean water.
- Do not smoke, eat or drink while handling the medicinal product.

If symptoms appear after exposure, such as skin rush, consult a doctor. Inflammation of the face, lips or eyes or breathing difficulty are very serious signs that require urgent medical attention.

4.6 Adverse reactions (frequency and seriousness)

None described at the recommended dose.

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

Bath with 95 g of formaldehyde/1000 L of water, equivalent to 250 ml of **AQUACEN-FORMALDEHYDE 380mg/ml** / 1000 L of water, for one hour.

In gilthead is considered a single application while in turbot, bathing will be done once a week for a maximum of 3 consecutive applications.

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

Do not exceed the recommended dose or application time.

Fish exposed to formaldehyde overdose showed a reduction in general activity, loss of balance and erratic swimming, followed by hypoactivity and death. The fish also developed erosions in skin and fins 4 hours after exposure to concentrations of 3 and 5 times the recommended therapeutic concentration.

In the event of overdose or if the fish show signs of stress, the treated water should be discarded and replaced with non-treated and well-oxygenated water.

4.11 Withdrawal period(s)
Zero degree-days.

5. PHARMACOLOGICAL PROPERTIES
Pharmacotherapeutic group: Ectoparasiticides, insecticides and repellents
ATCvet code: QP53AX19

5.1 Pharmacodynamic properties
Formaldehyde is an extremely reactive biocide that interacts with proteins, DNA and RNA interrupting cellular functions. High concentrations cause protein precipitation, generating cell death. It also acts as a mutagenic agent and as an alkylating agent by reacting with carboxyl, sulfhydryl and hydroxyl groups.
It is not known precisely which mechanism of formaldehyde is responsible for parasitary inactivation.

5.2 Pharmacokinetic particulars
Tests carried out dermally provide data of very low absorption dermically confirming that the aqueous formaldehyde solution does not penetrate the skin to an appreciable extent, even when applied on it.
Its half-life in circulating blood varies between 1 and 1.5 minutes in different species after intravenous administration, probably due to its rapid metabolism which would practically inhibit systemic distribution of the formaldehyde.
Formaldehyde can be metabolized through various routes: (1) incorporation in a pool of carbon compounds to be used in the biosynthesis of purines, thymidine and amino acids, (2) glutathione conjugation and oxidation by the formaldehyde dehydrogenase enzyme and (3) oxidation by catalase.
In addition, formaldehyde is formed endogenously during the metabolism of amino acids and xenobiotics.
Bibliographical information referring to fish shows that the application of formaldehyde in the form of baths at the recommended dose and even at higher levels does not produce higher formaldehyde levels in the tissues de treated fish than the endogenous levels in the control fish.

5.3 Environmental properties
The average life of formaldehyde in air (city air on a sunny day) is 1-2 hours.
Formaldehyde in water is biodegraded to low levels in a few days, the half-life in water is 36 hours.
The effects of formaldehyde on soil are unknown and there is no evidence of bioaccumulation.
Formaldehyde in a 35% aqueous solution undergoes biodegradation of 97.5% in 5 days.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Methanol
Purified water

6.2 Incompatibilities
Oxidizing substances.

Do not use in tanks to which any dye has been applied, such as methylene blue.

6.3 Shelf life

Shelf life of veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 6 months
Shelf life after dilution according to directions: 60 minutes

6.4. Special precautions for storage

Store below 30 °C
Store in the original container
Keep the barrel tightly closed.
Do not refrigerate or freeze. Protect from frost.

6.5 Nature and contents of immediate packaging

White 25 l barrels, made of high-density polyethylene, closed with high-density polyethylene screw caps and complex aluminum/high-density polyethylene disc for thermo induction.

Blue 200 l barrels, made of high-density polyethylene, closed with high-density polyethylene screw caps.

Blue 1,000 l barrels, made of high-density polyethylene, closed with high-density polyethylene screw caps.

Clear 1,000 l barrels, made of high-density polyethylene, closed with high-density polyethylene screw caps.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORIZATION HOLDER

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8. MARKETING AUTHORIZATION NUMBER(S)

9. DATE OF FIRST AUTHORIZATION OR DATE OF RENEWAL OF AUTHORIZATION

22nd February 2010

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE
Dispensing conditions: **Subject to veterinary prescription.**
Administration conditions: **To be administered by a veterinary surgeon or under their direct responsibility.**