

EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

GONAZON

EPAR summary for the public

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use. This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the Scientific Discussion (also part of the EPAR).

What is Gonazon?

Gonazon contains the active substance azagly-nafarelin. Gonazon is authorised as a concentrate that is made into a solution for injection for salmonid fish and also as an implant for dogs. Gonazon implant is rectangular in shape, off white, with dimensions of 14x3x1 mm.

What is Gonazon used for?

In fish, Gonazon is used to induce and synchronise ovulation (egg production) in female salmonids such as Atlantic salmon, rainbow trout, brown trout and Arctic charr for the production of eyed-eggs and fry. Following anaesthesia, the fish are injected intraperitoneally (into the area that contains the abdominal organs) along the central line, 1/2 to 1 fin length in front of the pelvic fin base. The recommended dose is 32 µg/kg body weight.

In bitches, Gonazon is also indicated for the prevention of gonadal function *via* long term blockade of gonadotrophin synthesis. Gonazon is injected subcutaneously, in the region of the umbilicus. The implant may be administered to bitches from the age of four months (blocking reproductive function for an average of 12 months) to 6 years (blocking reproductive function for an average of 11 months).

How does Gonazon work?

Gonazon contains azagly-nafarelin, which is an analogue of a natural hormone called gonadotrophin-releasing hormone (GnRH). GnRH controls reproduction in fish by increasing the secretion of the gonadotrophins controlling egg production.

In dogs, administration of higher doses of GnRH agonists over a period of time desensitises the pituitary gland with the result that release of gonadotrophins is suppressed, leading to a suppression of reproductive function.

How has Gonazon been studied?

In fish, Gonazon has been studied in three studies of rainbow trout, two studies of Atlantic salmon, and one study of Arctic charr. The main measure of effectiveness was the speed of response to treatment and the advance in time and synchronisation of the spawning period.

In bitches, the results of two field studies with Gonazon implants were provided, one investigating a single administration, another one the repeated application over a second year. Bitches treated with Gonazon generally failed to display heat during the study compared to bitches who did not receive the treatment. Good efficacy has been demonstrated for the prevention of heat and ovulation in adult bitches aged up to 7 years during the one or two years of treatment. Data on the return to oestrus, ovulatory oestrus and subsequent fertility once treatment has ended (i.e. once the implant had been removed) were limited, especially for repeated treatment.

What benefit has Gonazon shown during the studies?

In fish, the results of the trials showed that Gonazon was effective to induce and synchronise ovulation. In most cases, an effect was induced within 6-11 days of treatment, and ovulation was generally advanced by 2-3 weeks. The use of Gonazon while not necessarily improving reproductive performance over the course of the spawning season, by synchronising spawning will shorten the time span dedicated to eyed egg production. This optimises organisation of the fish farm.

In bitches, it has been demonstrated that the insertion of a Gonazon implant will prevent heat and ovulation in adult bitches aged up to 7 years during the one or two years of treatment.

What is the risk associated with Gonazon?

In fish, the injection of Gonazon may be associated with a reduction in fecundity (ability to breed), egg quality and survival to the eyed-egg stage. In some cases this can be caused by use of Gonazon too early in the spawning season.

In bitches, Gonazon works by inhibition of the production of sex steroids and may be associated with rare cases of vaginitis in prepubertal females.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

Operators should wear gloves when mixing the concentrate solution or handling the implant and avoid self injection.

In case of accidental contact with either the skin or the eyes, rinse thoroughly with water. If the concentrated solution or the diluted solution is spilled onto the skin or into the eyes, or the implant is accidentally self-injected, medical advice should be sought immediately. The package leaflet or the label should be shown to the doctor. Operators should wash their hands after use of the product.

Why has Gonazon been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) agreed that the benefits of Gonazon are greater than any risks for the induction and synchronisation of ovulation for the production of eyed-eggs and fry. Gonazon implants are effective in prevention of gonadal function via long term blockade of gonadotrophin synthesis. The CVMP recommended that Gonazon should be given a marketing authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

Other information about Gonazon:

The European Commission granted a marketing authorisation valid throughout the European Union, for Gonazon to Intervet International BV on 22 July 2003. Gonazon implants were authorised by an extension application, granted by the European Commission in January 2007. Information on the prescription status of this product may be found on the labelling.

This summary was last updated in December 2006.