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Public statement on

Gonazon (azagly-nafarelin)

Withdrawal of the marketing authorisation in the European Union

On 20 July 2003 the European Commission issued a marketing authorisation valid throughout the European Union for the veterinary medicinal product Gonazon (azagly-nafarelin). For female salmonid fish such as Atlantic salmon (Salmo salar), rainbow trout (Oncorhynchus mykiss), brown trout (Salmo trutta) and Arctic charr (Salvelinus alpinus), the therapeutic indication is the induction and synchronisation of ovulation for the production of eyed-eggs and fry.

For dogs, the therapeutic indication is the prevention of gonadal function in bitches via long term blockade of gonadotrophin synthesis.

The marketing authorisation holder (MAH) responsible for Gonazon was Intervet International BV. The European Commission was notified by a letter dated 10 February 2012 of the MAH's decision to voluntarily withdraw the marketing authorisation as of the Commission Decision date for Gonazon for commercial reasons.

On 19 March 2012 the European Commission issued a decision to withdraw the marketing authorisation for Gonazon.

Pursuant to this decision the European Public Assessment Report for Gonazon has been updated to reflect that the marketing authorisation is no longer valid.

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