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EPAR summary for the public

Improvac

gonadotropin releasing factor (GnRF) analogue-protein conjugate

This is a summary of the European public assessment report (EPAR) for Improvac. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use. It is not intended to provide practical advice on how to use Improvac.
For practical information about using Improvac, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

What is Improvac and what is it used for?

Improvac is a veterinary medicine used in male pigs to reduce 'boar taint' in the meat obtained from them after slaughter. Boar taint is the offensive odour or taste which may be present in pork or pork products from non-castrated mature male pigs. Boar taint is caused by the production and build-up of the natural compounds androstenone and skatole in the flesh of these animals. Improvac is used as an alternative to physical castration (removal of the testes) to reduce the presence of these compounds. Improvac also reduces aggressive and sexual (mounting) behaviour in pigs.

Improvac contains the active substance gonadotropin releasing factor (GnRF) analogue-protein conjugate.

How is Improvac used?

Improvac is available as a solution for injection and can only be obtained with a prescription. Improvac is given to male pigs as two injections with at least a 4 week interval. The first injection is from 8 weeks of age and the second 4 to 6 weeks before slaughter. The injection is given under the skin in the neck just behind the ear. Improvac starts to be effective within 1 week after the second injection. Androstenone and skatole levels are reduced from 4 to 6 weeks after the second injection and reduction of aggression and sexual behaviour is seen from 1 to 2 weeks after the second injection.

For further information, see the package leaflet.

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How does Improvac work?

The active substance in Improvac is an analogue of (similar to) gonatadotropin releasing factor (GnRF) linked to a carrier protein obtained from the bacterium *Corynebacterium diphtheriae*. Improvac works by stimulating the pig's immune system to produce antibodies against gonadotropin-releasing hormone (GnRH), part of the system that controls sexual development. This temporarily inhibits release of steroids from the testicles, including androstenone, one of the two causes of boar taint. Skatole, the other major cause of boar taint, is produced in the intestines and levels are reduced since the reduced level of sex hormones allows the liver to metabolise (break it down) more efficiently.

Improvac also contains a compound derived from the sugar dextran as an adjuvant (ingredient that strengthens the immune response).

What benefits of Improvac have been shown in studies?

In a number of field studies pigs treated with Improvac were comparable to surgically castrated pigs in terms of levels of androstenone and skatole at slaughter. In addition Improvac treated pigs had reduced blood levels of testosterone. The first injection had a limited effect, but the second injection is followed by production of antibodies against GnRF. The levels of antibodies decline with time but are still high enough to be reliably effective 4 to 6 weeks after the second injection.

Three field studies investigated the effectiveness of Improvac in reducing aggression and sexual behaviour in pigs. Two studies showed reduction of aggression and mounting from 1 to 2 weeks after the second injection of Improvac, while the third studied the long term effect on aggression and mounting after 4 weeks only.

What are the risks associated with Improvac?

The most common side effects with Improvac (which may affect more than 1 in 10 pigs) are injection site swelling, which gradually resolves but in 20 to 30% of animals will last for more than 6 weeks, and a short-lived increase in body temperature of around 0.5 °C within 24 hours of vaccination.

For the full list of restrictions and all side effects reported with Improvac, see the package leaflet.

Improvac must not be given to female pigs or to male pigs intended for breeding.

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

Safety information has been included in the summary of product characteristics and the package leaflet for Improvac, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers.

Accidental self-injection of Improvac may produce similar effects in people to those seen in pigs. These may include a temporary reduction in sex hormone levels and reduced ability to reproduce in men and in women, including problems with pregnancy. The risk of these effects occurring is greater after a second or subsequent accidental injection than after a first injection. Special care should be taken to avoid accidental self-injection. Improvac must only be used with a safety device including a needle guard and a mechanism to prevent accidental operation of the trigger. In case of accidental self-injection, medical advice should be sought immediately and the package leaflet or label shown to the doctor.

Improvac must not be given to pigs by women who are or who may be pregnant.

In case of skin or eye contact the affected area should be rinsed immediately with water.

What is the withdrawal period in food-producing animals?

The withdrawal period is the time required after administration of a medicine before an animal can be slaughtered and the meat used for human consumption.

The withdrawal period for meat from pigs treated with Improvac is 'zero' days, which means there is no mandatory waiting time.

Why is Improvac approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Improvac's benefits are greater than its risks and recommended that it be approved for use in the EU.

Other information about Improvac?

The European Commission granted a marketing authorisation valid throughout the EU for Improvac on 11 May 2009.

The full EPAR for Improvac can be found on the Agency's website: ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports. For more information about treatment with Improvac, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in September 2017.