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EPAR summary for the public

Imrestor

pegbovigrastim

This is a summary of the European public assessment report (EPAR) for Imrestor. 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 Imrestor.

For practical information about using Imrestor, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

What is Imrestor and what is it used for?

Imrestor is a veterinary medicine used as an aid in a herd management programme, to reduce the risk of clinical mastitis (inflammation of the udder) in dairy cows and heifers (cows that have not produced a calf) during the 30 days following calving. It contains the active substance pegbovigrastim.

For further information, see the package leaflet.

How is Imrestor used?

The medicine can only be obtained with a prescription and is available as a solution for injection in pre-filled syringes. The content of a single pre-filled syringe is given by injection under the skin (subcutaneously) to a dairy cow/heifer preferably 7 days before the anticipated date of calving. A second injection is given within 24 hours after calving. The intervals between the two injections should not be less than 3 days or more than 17 days.

For further information, see the package leaflet.

How does Imrestor work?

Pegbovigrastim is a modified form of a natural protein, bovine granulocyte colony stimulating factor (bG-CSF), that stimulates the production and activity of a type of white blood cells called neutrophils. Neutrophils are part of the immune system (the body's natural defences) and help to fight infection. By

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giving Imrestor, the number of neutrophils in the blood is increased, which is an aid to reduce the risk of infections of the udder that might lead to mastitis.

What benefits of Imrestor have been shown in studies?

In a field trial involving 2465 cows the incidence of clinical mastitis during days 3 to 30 of milk production was 9.1% (113/1235) in the Imrestor-treated group compared with 12.4% (152/1230) in the group given a dummy injection. The relative reduction in mastitis incidence was 26%.

What are the risks associated with Imrestor?

The most common side effects with Imrestor (which may affect up to 1 in 100 cows) are non-typical anaphylactoid (allergic) reactions seen as swelling of mucous membranes (notably vulva and eyelid), skin reactions, increased respiration rate and salivation. These clinical signs typically appear between 30 minutes and 2 hours after the first dose and resolve within 2 hours. Symptomatic treatment may be required.

For the full list of all side effects reported with Imrestor, see the package leaflet.

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

People who are hypersensitive (allergic) to pegbovigrastim should avoid contact with Imrestor.

In case of accidental self-injection, medical advice should be sought immediately and the package leaflet or label shown to the doctor. Headache and bone and muscle pain may occur. There may also be other effects including nausea (feeling sick), and rashes or other hypersensitivity reactions (e.g. breathing difficulties and low blood pressure).

Personal protective equipment consisting of gloves should be worn when handling broken or damaged syringes. Gloves should be removed and hands and exposed skin washed after use.

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. It is also the time required after administration of a medicine before milk may be used for human consumption.

The withdrawal period for meat and milk from cows treated with Imrestor is ‘zero’ days, which means there is no mandatory waiting time.

Why is Imrestor approved?

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

Other information about Imrestor

The European Commission granted a marketing authorisation valid throughout the EU for Imrestor on 09/12/2015.

The full EPAR for Imrestor 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 Imrestor, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in October 2015.