EMA/CVMP/193329/2007
EMEA/V/C/000051

EPAR summary for the public

Bovalto Ibraxion

Bovine rhinotracheitis vaccine (inactivated)

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

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

What is Bovalto Ibraxion and what is it used for?

Bovalto Ibraxion is a veterinary vaccine used to protect cattle against infectious bovine rhinotracheitis (IBR) virus. IBR virus infections affect the airways with nasal discharge, conjunctivitis (inflammation of the eye) and coughing.

Bovalto Ibraxion contains the active substance inactivated gene deleted IBR virus.

How is Bovalto Ibraxion used?

Bovalto Ibraxion is available as an emulsion and can only be obtained with a prescription. The vaccine is given into the neck at the front of the shoulder. Two injections are given 3 weeks apart to calves from age 2 weeks provided they have not acquired antibodies against IBR virus from the mother. When there are antibodies the vaccine should be given to calves from age 3 months. A booster injection is given at 6 month intervals.

Protection starts 2 weeks after vaccination and lasts for 6 months.

For further information, see the package leaflet.

How does Bovalto Ibraxion work?

Bovalto Ibraxion is a vaccine containing a version of the IBR virus that has been made inactive so it cannot cause infection. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. When Bovalto Ibraxion is given to cattle the animals' immune system recognises the inactive virus as 'foreign' and makes antibodies against it.

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In the future, if the animals are exposed to the active virus the immune system will be able to respond more quickly. The virus in the vaccine has also been modified to allow vaccinated animals to be distinguished from naturally infected animals so allowing better disease management.

Bovalto Ibraxion contains the adjuvant light paraffin oil to enhance the immune response.

What benefits of Bovalto Ibraxion have been shown in studies?

Field studies were conducted in around 300 cattle of various ages in both an IBR contaminated and an IBR free environment. Cattle vaccinated with Bovalto Ibraxion had protective levels of antibodies to IBR virus at 2 weeks after vaccination and the duration of protection was shown to last 6 months.

What are the risks associated with Bovalto Ibraxion?

The injection of Bovalto Ibraxion may cause a temporary tissue reaction at the site of injection, which may last for three weeks and rarely up to five weeks. Ibraxion may cause a slight rise in body temperature (less than 1°C) for less than 48 hours after injection. This does not affect the health or performance of the animal.

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

Bovalto Ibraxion is an emulsion containing mineral oil. Accidental injection may cause severe pain and swelling, particularly if injected into a joint or finger –this could result in the loss of a finger if prompt medical attention is not given. If someone is accidentally injected with this product, they must seek medical attention immediately even if only a very small amount is injected. The package leaflet should be shown to the doctor. If pain persists for more than 12 hours after medical examination, the doctor should be contacted again.

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 cattle treated with Bovalto Ibraxion is ‘zero’ days, which means there is no mandatory waiting time.

Why is Bovalto Ibraxion approved?

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

Other information about Bovalto Ibraxion?

The European Commission granted a marketing authorisation valid throughout the EU for Bovalto Ibraxion on 9 March 2000.

The name of the medicine was changed to Bovalto Ibraxion on 10 August 2016.

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

This summary was last updated in August 2016.