EMA/574388/2017
EMEA/V/C/004776

EPAR summary for the public

Bovilis Blue-8

bluetongue virus vaccine, serotype 8 (inactivated)

This is a summary of the European public assessment report (EPAR) for Bovilis Blue-8. 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 Bovilis Blue-8.

For practical information about using Bovilis Blue-8, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

What is Bovilis Blue-8 and what is it used for?

Bovilis Blue-8 is a vaccine used in cattle and sheep to protect them against bluetongue disease, an infection caused by the bluetongue virus, which is transmitted by midges. Clinical signs of the disease include fever, skin ulceration, as well as swelling and occasionally blueish discolouration of the tongue mainly seen in sheep. The vaccine is used to prevent viraemia (the presence of viruses in the blood) and to reduce clinical signs caused by bluetongue virus in sheep and to prevent viraemia in cattle. The vaccine contains inactivated (killed) bluetongue virus, serotype 8.

This medicine is the same as Bluevac BTV8, which is already authorised in the EU. The company that makes Bluevac BTV8 has agreed that its scientific data can be used for Bovilis Blue-8 ('informed consent').

How is Bovilis Blue-8 used?

The vaccine is available as a suspension for injection and can only be obtained with a prescription.

The vaccine is given to cattle and sheep as two injections under the skin. The first injection is given from two and a half months of age and a second injection is given three weeks later. For booster vaccination a single injection is given every year. Protection starts 31 days after the second injection in cattle and 20 days after the second injection in sheep. Protection lasts for one year.

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How does Bovilis Blue-8 work?

Bovilis Blue-8 is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Bovilis Blue-8 contains a bluetongue virus that has been inactivated so that it cannot cause the disease. When it is given to cattle and sheep, the animals' immune system recognises the virus as 'foreign' and produces antibodies against it. In the future, if the animals are exposed to the same type of bluetongue virus, the immune system will be able to produce antibodies more quickly. This will help to protect against the disease.

Bovilis Blue-8 contains bluetongue viruses of one type ('serotype 8'). The vaccine also contains 'adjuvants' (aluminium hydroxide and saponin) to stimulate a better reaction by the immune system.

What benefits of Bovilis Blue-8 have been shown in studies?

The effectiveness of the vaccine was investigated in a number of laboratory trials in sheep and cattle of the minimum recommended age. The main measures of the effectiveness of the vaccine were viraemia (levels of BTV8 in the blood) and clinical signs of bluetongue virus infection. In all studies the vaccinated sheep and cattle were compared with unvaccinated animals (controls). The studies showed that the vaccine prevents viraemia in sheep and cattle and reduces clinical signs in sheep when infected with bluetongue virus serotype 8.

What are the risks associated with Bovilis Blue-8?

The most common side effect with Bovilis Blue-8 (which may affect up to 1 in 10 animals) is an increase in body temperature between 0.5 and 1.0°C that lasts no longer than one to two days.

For the full list of restrictions and all side effects reported with Bovilis Blue-8, see the package leaflet.

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

No special precautions are required.

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 and sheep treated with Bovilis Blue-8 is 'zero' days, which means there is no mandatory waiting time.

Why is Bovilis Blue-8 approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Bovilis Blue-8's benefits are greater than its risks and recommended that it be approved for use in the EU.

Other information about Bovilis Blue-8:

The European Commission granted a marketing authorisation valid throughout the EU for Bovilis Blue-8 on 21 November 2017.

This authorisation was based on the authorisation granted to Bluevac BTV8 in 2011 ('informed consent').

The full EPAR for Bovilis Blue-8 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 Bovilis Blue-8, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in September 2017.