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Bluevac BTV (*bluetongue virus vaccine serotypes 1 or 4 or 8 [inactivated]*)[1]

An overview of Bluevac BTV and why it is authorised in the EU

What is Bluevac BTV and what is it used for?

Bluevac BTV 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. Signs of the disease include fever and skin ulceration, as well as swelling and occasionally blueish discolouration of the tongue mainly seen in sheep. The vaccine is used to prevent viraemia (presence of viruses in the blood) caused by bluetongue virus serotypes 1, 4 or 8 in sheep and cattle and to reduce clinical signs caused by serotype 8 in sheep. The vaccine contains inactivated (killed) bluetongue virus serotypes 1, 4 or 8.

How is Bluevac BTV used?

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

In sheep, the vaccine is given from 2.5 months of age. For bluetongue virus serotype 1 or serotype 4, one injection is given. For serotype 8, two injections are given 3 weeks apart.

In cattle, the vaccine is given from 2 months of age. For all serotypes, two injections are given 3–4 weeks apart.

For booster vaccination of cattle and sheep, a single injection is given every year.

Protection lasts for one year. In sheep, protection for all serotypes starts 21 days after completion of the primary vaccination scheme. In cattle, protection starts 28 days after completion of the primary vaccination scheme for serotype 1, 21 days for serotype 4 and 31 days for serotype 8.

For more information about using Bluevac BTV, see the package leaflet or contact your veterinarian or pharmacist.

How does Bluevac BTV work?

Bluevac BTV is a vaccine. Vaccines work by preparing the immune system (the body's natural defences) to defend the body against a disease. Bluevac BTV contains a bluetongue virus that has

[1] Previously known as Bluevac BTV8.

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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 makes antibodies against it. In the future, if the animals come into contact with the same type of bluetongue virus, these antibodies, together with other components of the immune system, will be able to fight off the virus more effectively and so help to protect the animal against the disease.

Bluevac BTV contains bluetongue viruses of one type (serotype 1, 4 or 8). The vaccine also contains 'adjuvants' (aluminium hydroxide and saponin) to stimulate a better reaction by the immune system.

What benefits of Bluevac BTV have been shown in studies?

The effectiveness of the vaccine was investigated in a number of laboratory and field trials in sheep and cattle. The main measures of the effectiveness of the vaccine were viraemia (levels of BTV in the blood) and clinical signs of bluetongue virus infection. In all studies the vaccinated sheep and cattle were compared with unvaccinated animals. The studies showed that the vaccine prevents viraemia in sheep and cattle and reduces clinical signs in sheep when infected with bluetongue virus serotype 1, 4 or 8.

What are the risks associated with Bluevac BTV?

The most common side effect with Bluevac BTV (which may affect more than 1 in 10 animals) is a temporary, normally painless nodule of 0.5 to 5 cm at the injection site. The nodules decrease in size over time and have usually disappeared by 21 days after administration.

For the full list of restrictions and side effects with Bluevac BTV, see the package leaflet.

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

In case of accidental self-injection, medical advice should be sought immediately and the package leaflet or label shown to the doctor.

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 Bluevac BTV is 'zero' days, which means that there is no mandatory waiting time.

Why is Bluevac BTV authorised in the EU?

The European Medicines Agency decided that Bluevac BTV's benefits are greater than its risks and it can be authorised for use in the EU.

Bluevac BTV was originally authorised under 'exceptional circumstances' because, as bluetongue disease falls under national disease control programmes, limited information was available at the time of authorisation. As the company had supplied the additional information requested, the 'exceptional circumstances' ended on 15 March 2016.

Other information about Bluevac BTV

Bluevac BTV received a marketing authorisation valid throughout the EU on 14 April 2011.

The name of the medicine was changed from Bluevac BTV8 to Bluevac BTV on 18 June 2020.

Further information on Bluevac BTV can be found on the Agency's website: ema.europa.eu/medicines/veterinary/EPAR/bluevac-btv.

This overview was last updated in 08-2020.