EMA/121814/2017
EMEA/V/C/004185

Zulvac BTV (*inactivated bluetongue vaccine containing either serotype 1, 4 or 8*)[1]

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

What is Zulvac BTV and what is it used for?

Zulvac BTV is a vaccine used in sheep and cattle to protect them against bluetongue disease, an infection caused by the bluetongue virus, which is transmitted by midges.

The vaccine contains inactivated (killed) bluetongue virus. When used in sheep the vaccine contains one of the following three vaccine strains: BTV serotype 1, BTV serotype 4 and BTV serotype 8.When used in cattle the vaccine contains either BTV serotype 1 or BTV serotype 8. The serotype to be used in the vaccine is selected before manufacture depending on which type is circulating and causing disease at the time. The vaccine can prevent the presence of serotypes 1 or 8 in the blood and reduce levels of serotype 4.

How is Zulvac BTV used?

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

The vaccine is given as two injections under the skin for sheep and in the muscle for cattle. The first injection is given from 6 weeks of age for sheep and from 12 weeks of age for cattle; and a second injection is given 3 weeks later. A booster is required after 12 months. For sheep protection starts 3 weeks after the initial course of two injections and lasts for one year. For cattle protection starts 15 days after the initial course of two injections for serotype 1 whilst protection starts 25 days after the initial course of two injections for serotype 8. Protection lasts for one year for both serotype 1 and 8.

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

How does Zulvac BTV work?

Zulvac BTV is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Zulvac BTV contains bluetongue virus that has been inactivated so that it cannot cause the disease. When it is given to sheep or cattle, their immune system recognises

[1] Previously known as Zulvac BTV Ovis.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

the virus as 'foreign' and makes antibodies against it. In the future, if the animals are exposed to the bluetongue virus, their immune system will be able to produce antibodies more quickly. This will help to protect them against the disease.

Zulvac BTV contains bluetongue virus of one type selected from serotypes 1, 4 and 8. The vaccine also contains 'adjuvants' (aluminium hydroxide and Quil-A) that enhance the response of the immune system.

What benefits of Zulvac BTV have been shown in studies?

Laboratory studies were conducted with the individual serotypes 1, 4 and 8 as well as with the combination of 1 and 8 in sheep which showed that protection starts three weeks after completion of the initial course of two injections for each serotype. Further laboratory studies showed protection lasts for one year for each serotype. A laboratory study with lambs vaccinated with serotype 4 showed the vaccine to reduce levels of serotype 4 in the blood for at least 12 months whilst studies with serotype 1 and 8 showed absence of the respective serotypes after one year.

Laboratory studies were conducted with the individual serotypes 1 and 8 in cattle which showed that protection starts 15 days after completion on the initial vaccination course of two injections for serotype 1 and 25 days after completion of the initial vaccination course for serotype 8. Further laboratory studies showed protection lasts for one year for the respective serotypes.

Data on the effectiveness under field conditions of other bluetongue virus vaccines containing the individual serotypes or a combination of two serotypes were also taken into account.

What are the risks associated with Zulvac BTV?

The most common side effects with Zulvac BTV in sheep (which may affect more than 1 in 10 animals) are a short-lived increase in body temperature, up to 1.6°C, during the 2 days after vaccination and local reactions at the injection site. In most cases the reactions are diffuse swellings at the injection site which last no longer than one week. They may also be nodules that can be felt under the skin of up to 60 cm^2 in size which reduce with time but may persist for more than 50 days.

The most common side effects with Zulvac BTV in cattle (which may affect more than 1 in 10 animals) are local reactions at the injection site and a short-lived increase in body temperature, up to 2.7°C, during the 2 days after vaccination. The local reactions lasted up to 25 days.

For the full list of restrictions, see the package leaflet.

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

None

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 sheep and cattle treated with Zulvac BTV is 'zero' days, which means there is no mandatory waiting time.

Why is Zulvac BTV authorised in the EU?

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

Other information about Zulvac BTV?

Zulvac BTV received a marketing authorisation valid throughout the EU on 25 April 2017.

The name of the medicine was changed to Zulvac BTV on 21 February 2019.

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

This summary was last updated in December 2018.