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Syvazul BTV (*inactivated bluetongue virus vaccine containing either serotype 1, 4 or 8 or a combination of any two*)

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

What is Syvazul BTV and what is it used for?

Syvazul 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 viruses. The variety (serotype) of the virus in the vaccine is selected depending on which serotypes are circulating and causing disease at the time of manufacture, so it may contain serotype 1, 4 or 8 or a combination of any two of these.

How is Syvazul BTV used?

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

Sheep

The vaccine is given as a single injection under the skin to sheep from 3 months of age. Revaccination is required after 1 year. The vaccine starts to be effective 39 days after vaccination and protection lasts for 1 year.

Cattle

The vaccine is given as two injections into a muscle to calves from 2 months of age if the calves have no immunity to bluetongue virus or from 3 months of age in calves born to mothers already immune to the disease. The second injection is given 3 weeks after the first. Revaccination with one injection is required after 1 year. The vaccine starts to be effective 21 days after completion of the initial vaccination course and protection lasts one year.

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

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How does Syvazul BTV work?

Syvazul BTV is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Syvazul BTV contains bluetongue viruses that have been inactivated so that they cannot cause the disease. When it is given to sheep and cattle, the animals' immune systems recognise the viruses as 'foreign' and make antibodies against them. 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.

Syvazul BTV contains bluetongue virus of one or two types selected from serotypes 1, 4 and 8. The vaccine also contains 'adjuvants' (aluminium hydroxide and saponin) that enhance the response of the immune system.

What benefits of Syvazul BTV have been shown in studies?

Laboratory studies were conducted in which sheep and cattle vaccinated with Syvazul BTV were exposed to BTV serotype 1, 4 or 8. The main measure of effectiveness was the presence of virus in the blood and the studies have shown that the vaccine is effective in producing protective antibodies in sheep and cattle.

Sheep

Laboratory studies showed that in sheep the vaccine starts to be effective 39 days after vaccination and protection lasts for 1 year. In a field study, 3 groups of 35 lambs from 3 months of age (with no antibodies to bluetongue virus) received vaccination with vaccines containing BTV-1, BTV-8 and BTV 1+8. Effectiveness was measured by comparing antibody levels to the virus at days 35 and 63 after vaccination with levels from laboratory studies. The data showed that antibody levels at day 63 after vaccination for each group remained at levels similar to day 35 after vaccination and above levels from the laboratory studies.

Cattle

Laboratory studies showed that in cattle the vaccine starts to be effective 21 days after completion of the initial vaccination course and protection lasts one year. Groups of 25 calves from 2 months of age (with no antibodies to bluetongue virus) were vaccinated with vaccines containing BTV-1, BTV-8 and BTV 1+8 in a field study. Effectiveness was measured by comparing antibody levels at 21 and 42 days after completing the initial vaccination course with levels from laboratory studies. The data showed that antibody levels at day 42 after vaccination for each group remained at levels similar to day 21 after vaccination and above levels from the laboratory studies.

No field studies were provided with BTV-4 in sheep or cattle, however, the laboratory studies were considered sufficient to show effectiveness of the BTV-4 vaccine.

What are the risks associated with Syvazul BTV?

The most common side effects with Syvazul BTV (which may affect more than 1 in 10 animals) are local injection site reactions, erythema (reddening of the skin) with mild to moderate swelling 1 to 6 days after vaccination, a painless nodule (up to 3.8 cm diameter in sheep and 7 cm diameter in cattle) 2 to 6 days after vaccination and a short-lived increase in body temperature of no more than 2.3°C in the 48 hours after vaccination.

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

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

Safety information has been included in the summary of product characteristics and the package leaflet for Syvazul BTV, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers.

People who are hypersensitive (allergic) to aluminium hydroxide, thiomersal or saponins should avoid contact with Syvazul BTV.

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 sheep and cattle treated with Syvazul BRV is 'zero' days, which means that there is no mandatory waiting time.

Why is Syvazul BTV authorised in the EU?

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

Other information about Syvazul BTV

Syvazul BTV received a marketing authorisation valid throughout the EU on 9 January 2019.

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

This overview was last updated in November 2018.