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EPAR summary for the public

Zulvac SBV

Schmallenberg virus vaccine (inactivated)

This is a summary of the European public assessment report (EPAR) for Zulvac SBV. 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 Zulvac SBV.

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

What is Zulvac SBV and what is it used for?

Zulvac SBV is a veterinary vaccine used to protect cattle and sheep from 3.5 months of age against Schmallenberg virus by reducing viraemia (presence of virus in the blood). Schmallenberg virus is transmitted by midges and causes stillbirths and birth defects in cattle and sheep.

Zulvac SBV contains the active substance inactivated (killed) Schmallenberg virus strain BH80/11-4.

How is Zulvac SBV used?

Zulvac SBV is available as a suspension for injection and can only be obtained with a prescription. The vaccine is given to cattle as two injections of 2 ml into the neck muscle three weeks apart and to sheep as a single injection of 1 ml under the skin behind the elbow. For female sheep vaccination should be at least two weeks before breeding to reduce viraemia (virus in the blood) and infection of the embryo during the first trimester of pregnancy.

For booster vaccination in cattle two injections of 2 ml should be given three weeks apart every 12 months. For booster vaccination in non-breeding sheep a single injection of 1 ml should be given every six months whilst in female breeding sheep a single injection of 1 ml should be given at least two weeks before breeding.

In cattle protection starts two weeks after vaccination and lasts 12 months. In sheep protection starts three weeks after vaccination and lasts six months.

How does Zulvac SBV work?

Zulvac SBV is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Zulvac SBV contains Schmallenberg virus that has been inactivated so that it cannot cause disease. When it is given to cattle or sheep, the animals' immune system recognises the virus as foreign and makes antibodies against it. In the future if the animals are exposed to Schmallenberg virus, the immune system will be able to produce antibodies more quickly. This will help protect them against the disease. The vaccine also contains 'adjuvants' (aluminium hydroxide and saponin) to enhance the immune response.

What benefits of Zulvac SBV have been shown in studies?

The effectiveness of Zulvac SBV has been investigated in laboratory studies in cattle and sheep. The animals were vaccinated according to the vaccination schedule and were then exposed to the Schmallenberg virus. The main measure of effectiveness was absence of viraemia following exposure to the virus.The studies showed that Zulvac SBV protects cattle two weeks and sheep three weeks after vaccination. In pregnant ewes vaccination reduced viraemia and infection of the embryo.

What are the risks associated with Zulvac SBV?

In cattle, an increase in body temperature of up to 1.5°C during the 48 hours after vaccination and the appearance of small lumps of up to 0.7 cm in diameter at the vaccination site that resolve within 10 days are very common (seen in more than 1 animal in 10).

In sheep more than one in ten animals may have an increase in body temperature of up to 1.5 °C during the 24 hours after vaccination. More than one in ten animals may show swellings or lumps of up to 8 cm in diameter under the skin at the injection site, and swellings less than 2 cm in diameter may last for at least 47 days.

In pregnant ewes more than one in ten animals may have an increase in body temperature of up to 0.8 °C during 4 hours after vaccination. More than one in ten animals may show swellings or lumps of up to 8 cm in diameter under the skin at the injection site, which may last for at least 97 days as granules less than 0.5 cm in diameter.

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.

The withdrawal period for meat from cattle and sheep treated with Zulvac SBV is 'zero' days, which means there is no mandatory waiting time.

Why is Zulvac SBV approved?

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

Other information about Zulvac SBV:

The European Commission granted a marketing authorisation valid throughout the EU for Zulvac SBV on 6 February 2015.

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

This summary was last updated in September 2015.