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EPAR summary for the public

BTVPUR AISap 1

Inactivated adjuvanted vaccine against bluetongue disease virus serotype 1

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use.

This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the scientific discussion (also part of the EPAR).

What is BTVPUR AISap 1?

BTVPUR AISap 1 is a vaccine that is available as a suspension for injection. It contains inactivated (killed) bluetongue serotype 1 virus.

What is BTVPUR AISap 1 used for?

BTVPUR AISap 1 is 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 is used to prevent viraemia (the presence of viruses in the blood) and reduce the signs of the disease.

The vaccine is given to young animals as two injections under the skin. The first injection is given from one month of age in animals that have never been exposed to the disease, and from two-and-a-half months if the animal's mother is already immune to the disease. The second injection is given three to four weeks later.

How does BTVPUR AISap 1 work?

BTVPUR AISap 1 is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. BTVPUR AISap 1 contains a bluetongue virus that has been inactivated so that it 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.

BTVPUR AISap 1 contains bluetongue virus of one types ('serotype 1'). The vaccine also contains 'adjuvants' (aluminium hydroxide and saponin) to enhance the immune response.

How has BTVPUR AISap 1 been studied?

The safety of the vaccine was studied in two main overdose laboratory safety studies carried out in sheep and cattle. Results also from a series of laboratory safety trials performed with vaccines of similar composition but including different bluetongue serotypes (including studies in pregnant ewes and cows) were presented in order to extrapolate safety conclusions.

The effectiveness of the vaccine was studied in three main laboratory trials using a vaccine with bluetongue serotype 1 in sheep and cattle of young age. The company also presented results from a series of trials conducted with vaccines of similar composition but including different serotypes from the one in BTVPUR AISap 1 in order to extrapolate further conclusions on the effectiveness of the vaccine.

Two studies were conducted in sheep and cattle to establish the period of protection provided by the vaccine.

What benefit has BTVPUR AISap 1 shown during the studies?

The studies showed that the vaccine is safe for sheep and cattle and that it reduces the signs of the disease and prevents viraemia in animals from one month of age that are infected with bluetongue virus serotype 1.

The studies also showed that the vaccine can be used in pregnant sheep and cattle as well as lactating cattle.

The duration of protection of the vaccine in both sheep and cattle was found to be 12 months.

What is the risk associated with BTVPUR AISap 1?

Vaccination may be followed by a small local swelling at the injection site, which normally resolves within five weeks. There can be a slight rise in body temperature, usually no more than 1 °C, in the 24 hours following vaccination.

What is the withdrawal period?

The withdrawal period is the time allowed after administration of the medicine before the animal can be slaughtered and the meat or milk used for human consumption. The withdrawal period for BTVPUR AISap 1 for meat and milk for cattle and sheep is zero days.

Why has BTVPUR AISap 1 been approved?

The CVMP concluded that the benefits of BTVPUR AISap 1 exceed the risks for active immunisation of sheep and cattle to prevent infection, viraemia and clinical signs caused by the bluetongue virus serotype 1, and recommended that BTVPUR AISap 1 be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

BTVPUR AISap 1 was initially authorised under 'exceptional circumstances'. This means that it was not possible to obtain complete information about BTVPUR AISap 1 at the time of the initial authorisation.

The European Medicines Agency (EMA) reviewed additional information submitted according to an agreed timetable on the quality, safety and efficacy of the vaccine. In 2013 the CVMP considered that the submitted data were adequate for the authorisation of BTVPUR AISap 1 to convert to a normal status.

Other information about BTVPUR AISap 1:

The European Commission granted a marketing authorisation valid throughout the European Union, for BTVPUR AISap 1 on 17 December 2010. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in February 2013.

Medicinal product no longer authorised