



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/116345/2009  
EMA/V/C/000146

## EPAR summary for the public

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### BTVPUR AISap 8

#### Inactivated vaccine against bluetongue disease virus, serotype 8

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 8?

BTVPUR AISap 8 is a vaccine that is available as a suspension for injection. It contains inactivated (killed) bluetongue serotype 8 virus.

#### What is BTVPUR AISap 8 used for?

BTVPUR AISap 8 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 caused by bluetongue virus serotype 8.

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

#### How does BTVPUR AISap 8 work?

BTVPUR AISap 8 is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. BTVPUR AISap 8 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 system recognises the viruses as 'foreign' and makes antibodies against them. In the future, if the animals are exposed to the bluetongue virus their immune systems will be able to produce antibodies more quickly. This will help to protect them against the disease.

BTVPUR AISap 8 contains bluetongue virus of one type ('serotype 8'). The vaccine also contains 'adjuvants' (aluminium hydroxide and saponin) to enhance the immune response.

### **How has BTVPUR AISap 8 been studied?**

The safety of the vaccine was studied in a number of laboratory safety studies carried out with BTVPUR AISap in sheep and cattle using a high dose of the vaccine in animals of the minimum age. Results from a series of laboratory safety trials performed with vaccines of similar composition but of different bluetongue serotypes were also presented in order to extrapolate safety conclusions, as the vaccine was initially intended for use in an emergency situation.

The efficacy of the vaccine in cattle was studied in a laboratory study using the vaccine in cattle from one month of age. Another laboratory study looked at the use of the vaccine in sheep aged three to four months. The duration of protection was also investigated in studies using sheep and cattle and was found to be 12 months for both species.

### **What benefit has BTVPUR AISap 8 shown during the studies?**

The studies showed that the vaccine is safe for sheep and cattle and that it prevents viraemia and reduces the signs of the disease in animals from one month of age that are infected with bluetongue virus serotype 8.

The studies also demonstrated that the vaccine can be used in pregnant sheep and cows. The effects of maternally derived antibodies were investigated and the vaccine was shown to be effective in animals from 2.5 months of age.

### **What is the risk associated with BTVPUR AISap 8?**

After vaccination, there can be a small swelling at the injection site lasting up to two weeks. Animals may show a temporary increase in body temperature, usually of no more than 1°C, in the 24 hours after vaccination.

### **What is the withdrawal period?**

The withdrawal period is the time allowed after administration of the medicine and before the animal can be slaughtered and the meat or milk used for human consumption. No withdrawal period for meat and milk with BTVPUR AISap 8 is necessary (zero days withdrawal period).

### **Why has BTVPUR AISap 8 been approved?**

The CVMP considered that the benefits of BTVPUR AISap 8 are greater than the risks and recommended that it be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

BTVPUR AISap 8 was initially authorised under 'exceptional circumstances'. This means that it was not possible to obtain complete information about BTVPUR AISap 8 at the time of the initial authorisation. Every year, the European Medicines Agency reviewed additional information according to an agreed

timetable on the quality, safety and efficacy of the vaccine. In 2012 the CVMP considered that the submitted data were adequate for the authorisation of BTPUR AISap 8 to convert to normal.

### **Other information about BTPUR AISap 8:**

The European Commission granted a marketing authorisation valid throughout the European Union for BTPUR AISap 8 on 17 March 2009. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated on 03/09/2012.

Medicinal product no longer authorised