EMA/CVMP/343593/2010
EMEA/V/C/139

EPAR summary for the public

BTVPUR AlSap 2-4

Bluetongue vaccine serotype 2 and 4

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 AlSap 2-4?

BTVPUR AlSap 2-4 is a vaccine. It is available as a suspension for injection that contains inactivated (killed) bluetongue serotype 2 and 4 viruses.

What is BTVPUR AlSap 2-4 used for?

BTVPUR ALSap 2-4 is used in sheep to protect them against bluetongue disease, an infection caused by the bluetongue virus which is transmitted by midges. The virus exists in several forms (serotypes) throughout the world; the types used in BTVPUR Alsap 2-4 are serotypes 2 and 4. 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 an injection under the skin. The 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 is likely to have inherited antibodies against the virus from a mother that is already immune to the disease. Protection starts three and five weeks after the injection for serotype 4 and serotype 2, respectively. Protection lasts for one year.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

An agency of the European Union

How does BTVPUR AlSap 2-4 work?

BTVPUR ALSap 2-4 is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. BTVPUR AlSap 2-4 contains bluetongue viruses that have been inactivated so that they cannot cause the disease. When it is given to sheep, the animals' immune systems recognise the viruses as 'foreign' and make antibodies against them. In the future, if the animals are exposed to bluetongue virus, the immune system will be able to produce antibodies more quickly. This will help to protect against the disease.

BTVPUR AlSap 2-4 contains bluetongue viruses of two types (serotypes 2 and 4). The vaccine also contains 'adjuvants' (aluminium hydroxide and saponin) to stimulate a better response.

How has BTVPUR AlSap 2-4 been studied?

The safety of the vaccine was studied in an overdose laboratory safety study carried out with BTVPUR AlSap 2-4 in sheep. Results also from a series of laboratory safety trials performed with vaccines of similar composition but including only one of the two serotypes of BTVPUR AlSap 2-4 or different bluetongue serotypes were presented in order to extrapolate safety conclusions.

The effectiveness of the vaccine in sheep was studied in a pivotal laboratory trial using the vaccine in sheep from a young age. Two more laboratory studies with BTVPUR AlSap 2-4 were presented to support the efficacy of the vaccine. The company also presented results from a series of trials conducted with vaccines of similar composition but including only one of the two serotypes of BTVPUR AlSap 2-4 in order to extrapolate further efficacy conclusions.

Two further studies were conducted to determine the period of protection of the monovalent vaccines each containing either bluetongue virus serotype 2 or 4 respectively. In both studies lambs were exposed to either bluetongue virus serotype 2 or bluetongue virus serotype 4, 12 months after vaccination.

What benefit has BTVPUR AlSap 2-4 shown during the studies?

The safety and effectiveness studies showed that the vaccine is safe for sheep 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 serotypes 2 and 4. The studies also showed that the vaccine can be used in pregnant and lactating sheep.

The studies on the monovalent vaccines containing bluetongue virus serotypes 2 or 4 showed that the period of protection is 12 months for both serotypes.

What is the risk associated with BTVPUR AlSap 2-4?

Vaccination may be followed by a small local swelling at the injection site (up to 24 cm^2) for a short period (up to two weeks).

Animals may show a slight rise in body temperature, normally no more than 1.1°C on average, 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 Alsap 2-4 for meat and milk for sheep is zero days.

Why has BTVPUR AlSap 2-4 been approved?

The CVMP concluded that the benefits of BTVPUR AlSap 2-4 exceed the risks for active immunisation of sheep to prevent infection, viraemia and clinical signs caused by the bluetongue virus serotypes 2 and 4, and recommended that BTVPUR AlSap 2-4 be given marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

BTVPUR AlSap 2-4 was initially authorised under 'exceptional circumstances'. This means that it was not possible to obtain complete information about BTVPUR AlSap 2-4 at the time of the initial authorisation. The European Medicines Agency (EMA) reviewed additional information according to an agreed timetable on the quality, safety and efficacy of the vaccine. In 2014 the CVMP considered that the submitted data were adequate for the authorisation of BTVPUR Alsap 2-4 to convert to a normal status.

Other information about BTVPUR AlSap 2-4:

The European Commission granted a marketing authorisation valid throughout the EU for BTVPUR AlSap 2-4 on 5 November 2010. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in February 2014.