

BTVPUR AISap 8 EU

Presentation

Suspension for injection containing inactivated Bluetongue Virus serotype 8 antigen, at least 7.1 CCID₅₀* per 1-ml dose, to stimulate active and specific immunity against Bluetongue Virus serotype 8 in cattle and sheep. Contains aluminium hydroxide and saponin as adjuvants.

*Equivalent to titre prior to inactivation (log 10).

Uses

For active immunisation of sheep and cattle to prevent viraemia* and to reduce clinical signs caused by Bluetongue Virus serotype 8.

*(below the level of detection by the validated RT-PCR method at 3.14log₁₀ RNA copies/ml, indicating no infectious virus transmission).

Onset of immunity has been demonstrated 3 weeks after the primary vaccination course. The duration of immunity is not yet fully established in cattle or sheep, although interim results of ongoing studies demonstrate that the duration is at least 6 months after the primary vaccination course in sheep.

Can be used during pregnancy in ewes. Safety throughout pregnancy in cows is not yet fully established, however interim results demonstrate safety in at least the last trimester of pregnancy in cows.

Dosage and administration

Apply usual aseptic procedures. Shake gently immediately before use. Avoid bubble formation, as this can be irritating at the site of injection. The entire content of the bottle should be used immediately after broaching and during the same procedure. Avoid multiple vial broaching.

Administer one dose of 1 ml subcutaneously according to the following vaccination scheme:

Primary vaccination

In sheep

- One injection: from 1 month of age in naive animals (or from 2.5 months of age in young animals born to immune sheep).

In cattle

- 1st injection: from 1 month of age in naive animals (or from 2.5 months of age in young animals born to immune cattle).
- 2nd injection: after 3-4 weeks

Revaccination

As the duration of immunity is not yet fully established in cattle or sheep, any revaccination scheme should be agreed by the Competent Authority or by the responsible veterinarian, taking into account the local epidemiological situation.

Contra-indications, warnings, etc

Keep out of the reach and sight of children.

For animal treatment only.

Vaccinate healthy animals only.

The safety and the efficacy of the vaccine has not been established in breeding males. In this category of animals the vaccine should be used only according to the benefit/risk assessment by the responsible veterinarian and/ or national Competent Authorities on the current vaccination policies against Bluetongue Virus (BTV).

If used in other domestic and wild ruminant species that are considered at risk of infection, its use in these species should be undertaken with care and it is advisable to test the vaccine on a small number of animals prior to mass vaccination. The level of efficacy for other species may differ from that observed in sheep and cattle.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be decided on a case by case basis.

Vaccination may be followed by a small local swelling at the injection site (at most 32 cm²) for a short period (at most 14 days). A transient increase in body temperature, normally not exceeding an average of 1.1°C, may occur within 24 hours after vaccination. No adverse reactions except these were observed after the administration of a double-dose of the vaccine.

Withdrawal period: Zero days.

Pharmaceutical precautions

Do not mix with any other veterinary medicinal product.

Store and transport refrigerated (2°C – 8°C). Protect from light. Do not freeze.

Shelf life of the veterinary medicinal product as packaged for sale: 1 year.

Shelf life after first opening the immediate packaging: immediately after broaching.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Legal category

POM-V

Package quantities

Box of 1 polypropylene bottle of 50 doses (1x 50 ml)

Box of 10 polypropylene bottles of 50 doses (10x 50 ml)

Box of 1 polypropylene bottle of 100 doses (1x100 ml)

Box of 10 polypropylene bottles of 100 doses (10x100 ml)

Box of 1 glass bottle of 10 doses (1x10ml)

Not all pack sizes may be marketed.

Marketing Authorisation number

(EU/2/09/094/001 – 005 (EMA/V/C/146)).