



BTVPUR AISap 8

Presentation

Suspension for injection containing Bluetongue Virus Serotype 8 antigen, at least 7.6 log₁₀ CCID₅₀* per 1-ml dose, to stimulate active immunity against Bluetongue Virus Serotype 8. Contains aluminium hydroxide and saponin as adjuvants.

*Equivalent to titre prior to inactivation (CCID₅₀: cell culture infectious dose 50%).

Uses

For active immunisation of sheep to reduce viraemia and clinical signs caused by Bluetongue Virus Serotype 8.

For active immunisation of cattle to reduce viraemia caused by Bluetongue Virus Serotype 8.

The onset of immunity has been demonstrated 3 weeks after the primary vaccination course. The duration of immunity has not yet been established.

The efficacy of the vaccine has not been fully established.

Dosage and administration

Shake gently immediately before use. Avoid bubble formation, as this can be irritating at the site of injection.

It is recommended to use a multiject type vaccination system when larger dose presentations are used.

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

Primary vaccination

In sheep: one injection from 3 months of age.

In cattle: two injections 1 month apart from 3 months of age.

Revaccination

The timing for administering booster vaccinations has not yet been established but it is recommended that animals are revaccinated at least 2 weeks before each risk period.

Contra-indications, warnings, etc

Keep out of the reach and sight of children.

For animal treatment only.

Vaccinate healthy animals only.

The safety of the vaccine in pregnant or lactating animals has not yet been established.

The vaccine has been tested for safety in sheep and cattle. If used in other ruminant species that are considered at risk of infection, 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 use of the vaccine in seropositive animals including those with maternally derived antibodies.

No information is available on the compatibility of this vaccine with any other vaccines. Therefore, the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

Vaccination may be followed by slight hyperthermia of short duration and a temporary local reaction at the injection site. In sheep, the local swelling may be moderate in size and usually persists for at least 14 days. In cattle, the local swelling may be large, although these reactions regress within one week to a moderate size and may persist for 8 weeks. On rare occasions an abscess may occur at the injection site.

Operator safety:

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

Withdrawal periods

Zero days.

Pharmaceutical precautions

Do not mix with any other medicinal product.

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

Once opened, use contents within 8 hours (provided the product is not subjected to extreme temperatures or contaminated).

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 10 polypropylene bottles of 100 doses (100 ml)

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

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

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

Not all pack sizes may be marketed.

Marketing authorisation number

Vm 17593/4006