

# Bovilis<sup>®</sup> BTV8 Suspension for injection

DATA SHEET **V**

## Presentation

Bovilis BTV8 is an inactivated vaccine containing per dose (1 ml) at least 500 Antigenic Units/ml of Bluetongue Virus Serotype 8 prior to inactivation. Aluminium hydroxide and Saponin are included as adjuvants.

## Uses

To stimulate active immunity against Bluetongue Virus Serotype 8 in cattle and sheep to reduce viraemia.

Onset of immunity: 3 weeks after vaccination.

Duration of immunity: Not yet established.

The efficacy of the vaccine has not been fully established.

## Dosage and administration

### Sheep

Sheep from 1 month of age: a single 1 ml dose by subcutaneous injection. The timing for administering booster vaccinations has not yet been established but it is recommended that animals are re-vaccinated at least 2 weeks before each risk period.

### Cattle

Cattle from 1 month of age: Two 1 ml doses administered with an approximate 3 week interval by subcutaneous injection. The timing for administering booster vaccinations has not yet been established but it is recommended that animals are re-vaccinated at least 2 weeks before each risk period.

Before using the vaccine allow it to reach ambient temperature (15 - 25°C).

Shake the bottle vigorously before use and periodically during use.

Ensure that vaccination equipment is clean and sterile before use.

It is recommended to use a multiject vaccination system.

## Contra-indications, warnings, etc.

Vaccinate healthy animals only.

The safety of use of the veterinary medicinal product in pregnant or lactating animals has not yet been established.

Immunisation may result in a slight rise in temperature (up to about 1°C) for up three days after vaccination and a temporary swelling at the injection site. In sheep these swellings typically last for up to three weeks while in cattle small palpable swellings may still be present up to six weeks after vaccination in approximately one third of vaccinates. Following administration of an overdose in sheep, swellings may still be palpable for at least six weeks.

This vaccine has been tested for safety in sheep and cattle. If used in other 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 use of the vaccine in seropositive animals including those with maternally derived antibodies.

### Interactions:

No information is available on the compatibility of this vaccine with any other.

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.

Do not mix with any other medicinal product.

### Operator warnings:

None.

### Withdrawal period:

Zero days.

For animal treatment only. Keep out of the reach and sight of children.

**Pharmaceutical precautions**

Store and transport at between + 2°C and + 8°C, protected from light. Do not freeze.  
Use within 8 hours of opening vial.

*Disposal advice:*

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

**Legal category**

**POM-V** To be supplied only on veterinary prescription.

The import, sale, supply and/or use of this veterinary medicinal product is only allowed under the particular conditions established by European Community legislation on the control of Bluetongue. Any person intending to import, sell, supply and/or use the veterinary medicinal product must be authorised by the competent authority of the member state.

**Package quantities**

Cardboard box with 1 or 10 PET or Type II glass vials of 10, 20, 50, 100, 250 and 500 ml. Not all presentations may be marketed.

**Further information**

Nil.

**Marketing Authorisation holder**

Vm 06376/4058

**Marketing Authorisation holder**

Intervet International BV represented by:  
Intervet UK Ltd  
Walton Manor, Walton,  
Milton Keynes, Bucks, MK7 7AJ

**Date of text preparation**

March 2008.