

## ZULVAC 8 BOVIS VACCINE DATA-SHEET

### Presentation

Per dose of 2ml:

Inactivated Blue Tongue Virus, serotype 8, strain BTV-8/BEL2006/02 titre  
≥106.7TCID50\*

(\*measured before inactivation)

Adjuvants:

Aluminium hydroxide gel (3%) 385.2mg (4 mg Al<sup>3+</sup>)

Saponins 0.4 mg

Excipient:

Thiomersal 0.2 mg

### Uses

Active immunisation of cattle from 2.5 months of age against Bluetongue Virus, serotype 8 to reduce viraemia.

Onset of immunity: 25 days after administration of the second dose.

Duration of immunity has not been established yet.

The efficacy of the vaccine has not been fully established.

### Dosage and administration

Administration route: Intramuscular.

Vaccination Schedule: Administer two doses (2ml) 3 weeks apart. First dose should be administered to animals from 2½ months of age. The timing for administering booster vaccinations has not been established but it is recommended that animals are re-vaccinated at least 2 weeks before each risk period.

### Contra-indications, warnings, etc

The effect of Maternally Derived Antibodies on vaccine efficacy has not been studied yet. The possible effect of vaccination on reproductive function in bulls (spermatogenesis) has not been studied. The safety of use of the veterinary medicinal product in pregnant or lactating cattle has not yet been established. 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 vaccine or immunological product.

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

Adverse Reactions: No adverse reactions were observed after administration of a double dose (4 ml) to calves. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

### Pharmaceutical precautions

Keep out of the reach and sight of children.

Store and transport refrigerated (2°C - 8°C).

Protect from light. Do not freeze.

Once broached use within one working day (8-10 hours).

### Legal category

POM-V

**Packaging Quantities**

Pack with one 20ml vial.

Pack with one 100ml vial.

Not all pack sizes may be marketed.

**Further information**

Disposal:

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

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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.

**Marketing authorisation number**

Vm 01596/4372.