1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bovilis Blue-8 suspension for injection for cattle and sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml of vaccine contains:

Active substance:
Bluetongue virus inactivated, serotype 8: $10^{6.5}$ $CCID_{50}$*
(* equivalent to titre prior to inactivation)

Adjuvants:
Aluminium hydroxide 6 mg
Purified saponin (Quil A) 0.05 mg

Excipient:
Thiomersal 0.1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
White or pinkish-white.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and cattle.

4.2 Indications for use, specifying the target species

Sheep
For the active immunisation of sheep from 2.5 months of age to prevent viraemia* and to reduce clinical signs caused by bluetongue virus serotype 8.
*(Cycling value (Ct) ≥ 36 by a validated RT-PCR method, indicating no presence of viral genome)

Onset of immunity: 20 days after the second dose.
Duration of immunity: 1 year after the second dose.

Cattle
For the active immunisation of cattle from 2.5 months of age to prevent viraemia* caused by bluetongue virus serotype 8.
*(Cycling value (Ct) ≥ 36 by a validated RT-PCR method, indicating no presence of viral genome)

Onset of immunity: 31 days after the second dose.
Duration of immunity: 1 year after the second dose.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

Occasionally, the presence of maternally derived antibodies in ovines of minimum recommended age might interfere with the protection induced by the vaccine.

No information is available on the use of the vaccine in seropositive bovines, including those with maternally derived antibodies.

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.

4.5 Special precautions for use

Special precautions for use in animals

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

An average increase in body temperature varying between 0.5 and 1.0 ºC is a common reaction observed in sheep and cattle. It lasted not longer than 24 to 48 hours. Transient fever was observed in rare cases. Temporary local reactions can occur very rarely at the injection site in the form of a nodule of 0.5 to 1 cm in sheep and of 0.5 to 3 cm in cattle which disappears within 14 days, at the latest and which may be painful. Loss of appetite can occur in very rare cases. Hypersensitivity reactions are very rarely observed.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy.

Lactation:
There is no negative impact on the milk yield using the vaccine in lactating ewes and cows.

Fertility:
The safety and efficacy of the vaccine has not been established in breeding males (sheep and cattle). 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).

4.8 Interaction with other medicinal products and other forms of interaction

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 made on a case by case basis.

4.9 Amounts to be administered and administration route

Subcutaneous use.

Shake well before use. Avoid multiple vial broaching. Avoid introduction of contamination.

Primary vaccination:

Sheep from 2.5 months of age:
Administer two doses of 2 ml subcutaneously with a 3 week interval.

Cattle from 2.5 months of age:
Administer two doses of 4 ml subcutaneously with a 3 week interval.

Revaccination:

1 dose per year.

Any revaccination scheme should be agreed by the competent authority or by the responsible veterinarian, taking into account the local epidemiological situation.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Occasionally a slight increase of the temperature (0.5 ºC – 1.0 ºC) is observed for 24–48 hours after the administration of a double dose of the vaccine. Painless swellings occur occasionally with a size up to 2 cm in sheep and up to 4.5 cm in cattle after a double dose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Bovidae/Ovidae, inactivated bluetongue virus vaccines.
ATCvet codes: Cattle: QI02AA08 / Sheep: QI04AA02

Bovilis Blue-8 stimulates active immunity against bluetongue virus, serotype 8.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide
Purified saponin (Quil A)
Thiomersal
Phosphate buffered saline (sodium chloride, disodium phosphate and potassium phosphate, water for injections)

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 10 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

High density polyethylene (HDPE) bottles of 52 ml, 100 ml or 252 ml with bromobutyl stoppers and aluminium seals.

Package sizes:
Cardboard box with 1 bottle containing either 26 sheep doses or 13 cattle doses (52 ml).
Cardboard box with 1 bottle containing either 50 sheep doses or 25 cattle doses (100 ml).
Cardboard box with 1 bottle containing either 126 sheep doses or 63 cattle doses (252 ml).

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Intervet International BV
Wim de Körverstraat 35
5831 AN Boxmeer
The NETHERLANDS

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/17/218/001-003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21/11/2017

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.