SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BTVPUR suspension for injection for sheep and cattle.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substances *:
Inactivated bluetongue virus ³ strain specific pass level (log10 pixels) **
(*) maximum of two different inactivated bluetongue virus serotypes

(**) Strain-specific pass levels	(**) Antigen content (VP2 protein) by immuno-assay
BTV1	1.9 log10 pixels/mL
BTV2	1.82 log10 pixels/mL
BTV4	1.86 log10 pixels/mL
BTV8	2.12 log10 pixels/mL

A confirmatory final potency test by seroneutralisation in rats is conducted when a batch is released.

Adjuvants:
Aluminium hydroxide (Al^{3+}) 2.7 mg
Saponin 30 HU**
(**) Haemolytic units

For the full list of excipients, see section 6.1.

The type of strain(s) (two strains at most) included in the final product will be selected based on the epidemiological situation at the time of manufacturing and will be stated on the label.

3. PHARMACEUTICAL FORM

Suspension for injection
Appearance: homogeneous milky white.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and cattle

4.2 Indications for use, specifying the target species

Active immunisation of sheep to prevent viraemia* and to reduce clinical signs caused by bluetongue virus serotypes 1, 2, 4 and/or 8 (combination of maximum 2 serotypes).

Active immunisation of cattle to prevent viraemia* caused by bluetongue virus serotypes 1, 2, 4 and/or 8, and to reduce clinical signs caused by bluetongue virus serotypes 1, 4 and/or 8 (combination of maximum 2 serotypes).
*below the level of detection by the validated RT-PCR method at 3.68 $\log_{10}$ RNA copies/ml, indicating no infectious virus transmission.

Onset of immunity: 3 weeks (or 5 weeks in sheep for BTV2) after the primary vaccination course for BTV-1, BTV-2 (cattle), BTV-4 and BTV-8 serotypes.

Duration of immunity: 1 year after primary vaccination course.

4.3 Contraindications

None.

4.4 Special warnings

Vaccinate healthy animals only.

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

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Sheep and cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reactions; Injection site swelling[1]; Elevated temperature[2].

[1]at most 32 cm² in cattle and 24 cm^2 in sheep, which becomes residual 35 days later (≤ 1 cm^2)
[2]not exceeding 1.7°C (with an average of 1.1 ºC), may occur within 24 hours after vaccination

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See section “Contact details” of the package leaflet.

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Fertility:
The safety and the efficacy of the vaccine have 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).

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 Amount(s) to be administered and administration route

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

- Second injection: after 3-4 weeks.
  For a monovalent vaccine containing an inactivated Bluetongue Virus serotype 2 or 4, or for a bivalent vaccine containing both serotypes 2 and 4 together, one injection is sufficient.

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

- **Revaccination**

Annual.

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

Very rare and transient apathy can be observed after the administration of a double-dose of the vaccine. No other adverse events except those mentioned in section 3.6 were observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL

Pharmacotherapeutic group: bluetongue virus vaccine

ATCvet Code: QI04AA02 (sheep) and QI02AA08 (cattle)
To stimulate active immunity against bluetongue virus in the vaccinated animal.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Silicon antifoam
Phosphate buffer
Glycine buffer
Aluminium hydroxide
Saponin

6.2 Major Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of monovalent or bivalent formulation with Bluetongue Virus serotypes 1, 8 (100 ml, 50 ml and 10 ml bottles) and/or 2, 4 (100 ml and 50 ml bottles): 2 years.
Shelf life of monovalent or bivalent formulation with Bluetongue Virus serotypes 2 and/or 4 (10 ml bottles): 18 months.
Shelf life after first opening the immediate packaging: use immediately.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Polypropylene bottle of 50 or 100 ml with butyl elastomer closure.
Box of 1 bottle of 100 doses (1 x 100 ml)
Box of 10 bottles of 100 doses (10 x 100 ml)
Box of 1 bottle of 50 doses (1 x 50 ml)
Box of 10 bottles of 50 doses (10 x 50 ml)

Type I glass bottle of 10 ml with butyl elastomer closure.
Box of 1 bottle of 10 doses (1 x 10 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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 04491/5007

9. DATE OF FIRST AUTHORISATION

17 December 2010

10. DATE OF REVISION OF THE TEXT

July 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product containing serotypes 1, 2, 4 and 8 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.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Approved 21 July 2023