PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 1 bottle of 10 ml,
Box of 1 bottle of 50 ml,
Box of 10 bottles of 50 ml,
Box of 1 bottle of 100 ml,
Box of 10 bottles of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BTVPUR suspension for injection for sheep and cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose of 1 ml contains:
Active substances *:

Inactivated Bluetongue Virus ≥ strain specific pass level (log_{10} 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

3. PACKAGE SIZE

10 doses (10 ml)
50 doses (50 ml)
10 x 50 doses (10 x 50 ml)
100 doses (100 ml)
10 x 100 doses (10 x100 ml)

4. TARGET SPECIES

Sheep and cattle

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once broached, use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Keep the bottle in the outer carton.

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

14. MARKETING AUTHORISATION NUMBERS

Vm 04491/5007

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V
To be supplied only on veterinary prescription

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (Bottle of 100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BTVPUR suspension for injection for sheep and cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose of 1 ml contains:
Active substances *:

Inactivated Bluetongue Virus ≥ strain specific pass level (log_{10} 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

3. TARGET SPECIES

Sheep and cattle

4. ROUTES OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: zero days

6. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once broached, use immediately.

7. SPECIAL STORAGE PRECAUTIONS

Keep the bottle in the outer carton.

Store and transport refrigerated.
Do not freeze.
Protect from light.

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

100 doses (100ml)

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY

13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

14. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

POM-V To be supplied only on veterinary prescription

15. MARKETING AUTHORISATION NUMBER(S)

Vm 04491/5007

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (Bottle of 10 and 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BTVPUR

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

1 ml dose*:
Inactivated BTV1 ≥ 1.9 log10 pixels
Inactivated BTV2 ≥ 1.82 log10 pixels
Inactivated BTV4 ≥ 1.86 log10 pixels
Inactivated BTV8 ≥ 2.12 log10 pixels
(*) maximum of two different inactivated bluetongue virus serotypes.

10 doses (10 ml)
50 doses (50 ml)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}

Once broached, use immediately.

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

6. ROUTE(S) OF ADMINISTRATION

SC

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BTVPUR suspension for injection for sheep and cattle

2. COMPOSITION

Each dose of 1 ml contains:

Active substance*:

Inactivated Bluetongue Virus ≥ strain specific pass level (log_{10} 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

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.

Appearance: homogeneous milky white.

3. TARGET SPECIES

Sheep and cattle.

4. INDICATIONS FOR USE

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 BTV1, BTV2 (cattle), BTV-4 and BTV-8 serotypes.

Duration of immunity: 1 year after primary vaccination course.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNING(S)

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.

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).

Interactions 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 decided on a case by case basis.

Overdose:
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 “Adverse Events” were observed.

Special restrictions for use and special conditions for 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.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. ADVERSE EVENTS

Sheep and cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Hypersensitivity reactions; injection site swelling[1] and 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

- **Primary vaccination**

In sheep

- 1st injection: from 1 month of age in naive animals (or from 2.5 months of age in young animals born to immune sheep).
- 2nd injection: after 3-4 weeks

For a monovalent vaccine containing an inactivated Bluetongue Virus serotypes 2 or 4, or for a bivalent vaccine containing both serotypes 2 and 4 together, one injection is sufficient.

In cattle

- 1st injection: from 1 month of age in naive animals (or from 2.5 months of age in young animals born to immune cattle).
- 2nd injection: after 3-4 weeks.

- **Revaccination**

Annual.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Shelf life after first opening the immediate packaging: use immediately.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 04491/5007

Not all pack sizes may be marketed
Box of 1 bottle of 10 doses (1 x 10 ml)
Box of 1 bottle of 50 doses (1 x 50 ml)
Box of 10 bottles of 50 doses (10 x 50 ml)
Box of 1 bottle of 100 doses (1 x 100 ml)
Box of 10 bottles of 100 doses (10 x 100 ml)

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

March 2023

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint-Priest
France

Local representative and contact details to report suspected adverse reactions:

Boehringer Ingelheim Animal Health UK Ltd,
Bracknell, RG12 8YS, UK

17. OTHER INFORMATION

The vaccine stimulates active immunity against Bluetongue Virus in the vaccinated animal.

For animal treatment only.

Approved 29 August 2023