## BTV Vaccines Comparison of Guidelines – Updated on 19th Sept 2024

|             | Bultavo-3   | BLUEVAC-3   | Syvazul BTV   |
|-------------|---|---|---|
| Company     | Boehringer Ingelheim                                  | Ceva Animal Health  | Virbac UK   |
| Contact for | 01344 746957 or vetenquiries@                         | 01628 334056 or   | 01359 243243 enquiries@virbac.co.uk or                        |
| information | boehringer-ingelheim.com                              | <u>rubu-uk@ceva.com</u>                                     | contact Virbac Territory Manager                              |
| Active      | Inactivated bluetongue virus serotype 3               | Bluetongue virus, serotype 3, strain BTV-                   | Bluetongue virus, serotype 3 (BTV-3), strain                  |
| substance   | (strain Bio-93:BTV3) ≥ 10 ELISA units                 | 3/NET2023, inactivated 10 <sup>6.5</sup> CCID <sub>50</sub> | BTV-3/NET2023, inactivated $\geq 10^{6.9}$ CCID <sub>50</sub> |
| Adjuvant    | Aluminium hydroxide                                   | Aluminium hydroxide   | Aluminium hydroxide (Al3+)                                    |
|             | Quillaja saponin (Quil A)                             | Purified saponin (Quil A)                                   | Purified saponin (Quil-A)                                     |
| Sheep       | Active immunisation to reduce viraemia                | For active immunisation of sheep to                         | For active immunization of sheep to                           |
|             | and to prevent clinical signs and                     | reduce the viraemia, preventing mortality                   | reduce viraemia, to prevent mortality and                     |
|             | mortality caused by bluetongue virus                  | and to reduce clinical signs caused by                      | reduce clinical signs and lesions caused                      |
|             | serotype 3.   | the serotype 3 of the bluetongue virus.                     | by bluetongue serotype 3.                                     |
|             | One dose - 1ml subcutaneously from                    | Sheep from 2 months of age: Administer                      | Administer subcutaneously to sheep from                       |
|             | one month old   | two doses of 2 mL subcutaneously 3                          | 3 months of age - Primary vaccination:                        |
|             |   | weeks apart.  | administer a single 2 ml dose                                 |
|             | Revaccination not established                         |   | Revaccination: administer one dose of 2                       |
|             |   | Revaccination not established                               | ml after 12 months  |
| Cattle      | Active immunisation against bluetongue                | For active immunisation of cattle to                        | For active immunization against                               |
|             | virus serotype 3.                                     | reduce the viraemia against the serotype                    | bluetongue virus serotype 3.                                  |
|             |   | 3 of the bluetongue virus.                                  |   |
|             | 1ml intramuscularly from one month                    |   | Administer intramuscularly to cattle from                     |
|             | old and then 2 <sup>nd</sup> injection 3 weeks later. | Cattle from 2 month of age: Administer                      | 2 months of age in naïve animals or from 3                    |
|             |   | two doses of 4 mL subcutaneously                            | months of age in calves born to immune                        |
|             |   | 3weeks apart.   | cattle - Primary vaccination: administer                      |
|             | Revaccination not established                         |   | two doses of 4 ml 3 weeks apart                               |
|             |   |   | Revaccination: administer one dose of 4                       |
|             |   | Revaccination not established                               | ml after 12 months.   |

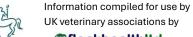


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|                       | Bultavo-3   | BLUEVAC-3   | Syvazul BTV  |
|-----------------------|---|---|--|
| Onset of              | 21 days after the primary vaccination                                       | 21 days after completion of primary   | 28 days after completion of the primary  |
| immunity:             | course in sheep.<br>Not established in cattle.                              | vaccination scheme in cattle & sheep  | vaccination scheme in sheep.<br>Not established in cattle.                     |
| Duration of immunity  | Not established for sheep or cattle   | Not established for sheep or cattle   | Not established for sheep or cattle  |
| Special precautions   | Vaccinate healthy animals only.   | Vaccinate healthy animals only.   | Vaccinate healthy animals only.  |
| Maternally<br>derived | High levels of maternal antibodies negatively affect the formation of post- | Occasionally, the presence of maternally-derived antibodies in sheep of         | No information is available on the use of the vaccine in sheep and cattle with |
| antibodies            | vaccination antibodies, which may affect the level of antibodies after      | minimum recommended age might interfere with the protection induced by          | maternally-derived antibodies.   |
|                       | vaccination. These maternally derived                                       | the vaccine.  |  |
|                       | antibodies usually disappear within 3 months of age in lambs and within 2.5 | No information is available on the use of the vaccine in cattle with maternally |  |
|                       | months of age in cattle.  | derived antibodies.   |  |
|                       | If used in other domestic and wild  | If used in other domestic and wild  | If used in other domestic and wild   |
|                       | ruminant species that are considered at                                     | ruminant species that are considered at   | ruminant species that are considered at  |
|                       | risk of infection, its use in these species                                 | risk of infection, its use in these species                                     | risk of infection, its use in these species                                    |
|                       | should be undertaken with care and it is                                    | should be undertaken with care and it is  | should be undertaken with care and it is                                       |
|                       | advisable to test the vaccine on a small                                    | advisable to test the vaccine on a small  | advisable to test the vaccine on a small                                       |
|                       | number of animals prior to mass   | number of animals prior to mass   | number of animals prior to mass  |
|                       | vaccination. The level of efficacy for                                      | vaccination. The level of efficacy for other                                    | vaccination. The level of efficacy for other                                   |
|                       | other species may differ from that  | species may differ from that observed in  | species may differ from that observed in                                       |
|                       | observed in sheep and cattle.   | cattle and sheep.   | sheep and cattle.  |
| Pregnancy             | Can be used during pregnancy.   | Can be used during pregnancy in ewes and cows.                                  | Can be used in pregnancy.  |
| Lactation             | Safety not established in lactation   | No negative impact on the milk-yield  | Can be used in lactation.  |
|                       |   | using the vaccine in lactating ewes and   |  |
|                       |   | cows is expected.   |  |



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Information compiled for use by UK veterinary associations by

|                         | Bultavo-3   | BLUEVAC-3   | Syvazul BTV   |
|-------------------------|---|---|---|
| Breeding<br>males       | Safety not established in breeding males  | Safety not established in breeding males  | Safety not established in breeding males.   |
|                         | Shake gently immediately before use.<br>Avoid bubble formation, as this can be<br>irritating at the site of injection. The<br>entire content of the bottle should be<br>used immediately after broaching and<br>during the same procedure. Avoid<br>multiple broaching of vials.<br>Before use the vaccine should be<br>warmed to 15-25°C.<br>Adverse events – Injection site swelling<br>and elevated temperature of<br>undetermined frequency in cattle &<br>sheep. | Adverse events (based on other Bluevac<br>vaccines)<br>Injection site nodule (painless 0.5-9cm<br>size, decreases in size & normally<br>disappeared within 21d) - very common<br>in cattle & sheep (>1 animal/10 treated)<br>Hyperthermia – common in sheep (1-10<br>animals /100 treated) & rare in cattle (1-<br>10 animals/10,000 treated)<br>Loss of appetite & hypersensitivity – very<br>rare in cattle & sheep (<1 animal/10,000<br>treated) | Adverse events - Injection site reaction,<br>Injection site erythema, Injection site<br>nodule, hyperthermia - very common in<br>cattle & sheep (>1 animal / 10 treated).<br>Injection site abscess – rare in cattle &<br>sheep (1-10 animals/10,000 treated)<br>Abortion, perinatal mortality, premature<br>parturition, Apathy, recumbency, fever,<br>anorexia, lethargy – rare in sheep (1-10<br>/10,000 and very rare in cattle (<1<br>animal/10,000 treated.<br>Milk production decrease, Paralysis,<br>ataxia, blindness, incoordination,<br>Pulmonary congestion, dyspnoea, Rumen<br>atony, bloated – very rare in sheep & cattle<br>(<1 animal/ 10,000 treated) |
| Withdrawal              | Zero days   | Zero days   | Zero days   |
| Shelf life              | 24 months as packaged<br>10 hours after first opening packaging   | 18 months as packaged<br>10 hours after first opening packaging   | 2 years as packaged<br>10 hours after opening immediate<br>packaging  |
| Storage<br>requirements | Store and transport refrigerated (2°C – 8°C). Do not freeze. Protect from light.  | Store and transport refrigerated (2 °C – 8 °C). Do not freeze. Protect from light.  | Store and transport refrigerated (2 °C – 8 °C). Do not freeze. Protect from light. Store in the original package.   |
| Packaging               | Bottles of 10 doses and 50 doses  | Box containing bottles of 52ml, 100ml<br>and 252 ml   | Box containing vials of 80ml or 200ml   |

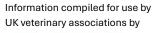


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|              | Bultavo-3                                  | BLUEVAC-3                                  | Syvazul BTV   |
|--------------|--|--|---|
| Additional   | "There is additional clinical work that is | "Expecting it within a few weeks."         | On 9 <sup>th</sup> September 2024 - "We are working |
| information  | not reflected in the SPC – we have both    |  | on it arriving towards the end of next week,        |
| supplied     | sheep and cattle challenge studies and     |  | or maybe beginning of the following week            |
| directly by  | the DOI work is underway. The clinical     |  |   |
| company by   | studies are currently being written up as  |  |   |
| email        | posters for the VetEpi conference."        |  |   |
| Information  | Only the 50-dose product will come         | Only the 252ml vials will be available in  | Syvazul arrives in the UK on 19/9/24.               |
| gleaned at   | into UK. 500k doses in Sept & a further    | <b>UK</b> (at all three wholesalers)       | Available for onward sale in w/c 23/9/24 at         |
| meetings     | 300k doses in October via all three        | Realistically will be 3 weeks away (likely | all three wholesalers.                              |
| with         | wholesalers. The company can pull in       | more likely 4-5 wks to be at practice).    |   |
| manufacturer | more if necessary.                         | Shelf life of vaccine that arrives will    |   |
| on 13.9.24   |  | probably be September 2025.                |   |
|              |  |  |   |

These vaccines have been used in goats and camelids in Europe & each of the companies may have more information that they can share with individual veterinary surgeons on a one-to-one basis. The British Veterinary Camelid Society and the Goat Veterinary Society have issued specific recommendations to their members that can also be accessed at <u>BTV3 - information for vets - Ruminant Health & Welfare (ruminanthw.org.uk)</u>.

The vaccines are currently un-authorised but the Secretary of State has granted *permission* for them to be used in cattle and sheep under *licence* (either general in high risk, or specific in other areas of England). If they are to be used, a veterinary prescription is needed and the licence rules must be followed. There is <u>guidance for vets</u> issued by the CVO which includes the following:

1. The vaccine should be prescribed, in writing or digitally, by the private veterinary surgeon (PVS) normally responsible for the care of the animals intended to receive it.

2. The PVS should keep, and retain for at least 5 years, a written or digital record (which should be provided to an inspector if required) of: a. The number of doses ordered from the wholesaler. b. The number of doses supplied to animal keepers.

3. The prescribing PVS should notify Defra (exotic.disease.policy@defra.gov.uk) within 7 days of prescribing the vaccine, of the below information: a. The CPH where the animals are located at the time of prescribing. b. The vaccine product name and batch number. c. The species and number of animals the prescription is intended for. d. Any special instructions contained within the prescription.

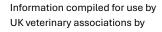
4. Any adverse side effects associated with the vaccine, including suspected lack of efficacy, should be reported within 7 calendar days to the relevant pharmaceutical company (as detailed on the package leaflet) or the Veterinary Medicines Directorate.











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