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

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Onset of immunity:	21 days after the primary vaccination course in sheep. Not established in cattle.	21 days after completion of primary vaccination scheme in cattle & sheep	28 days after completion of the primary vaccination scheme in sheep. 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 derived antibodies	High levels of maternal antibodies negatively affect the formation of post-vaccination antibodies, which may affect the level of antibodies after vaccination. These maternally derived antibodies usually disappear within 3 months of age in lambs and within 2.5 months of age in cattle.	Occasionally, the presence of maternally-derived antibodies in sheep of minimum recommended age might interfere with the protection induced by the vaccine. No information is available on the use of the vaccine in cattle with maternally derived antibodies.	No information is available on the use of the vaccine in sheep and cattle 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.	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 cattle and sheep.	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	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 using the vaccine in lactating ewes and cows is expected.	Can be used in lactation.

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Breeding males	Safety not established in breeding males	Safety not established in breeding males	Safety not established in breeding males.
	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 broaching of vials. Before use the vaccine should be warmed to 15-25°C. Adverse events – Injection site swelling and elevated temperature of undetermined frequency in cattle & sheep.	Adverse events (based on other Bluevac vaccines) Injection site nodule (painless 0.5-9cm size, decreases in size & normally disappeared within 21d) - very common in cattle & sheep (>1 animal/10 treated) Hyperthermia – common in sheep (1-10 animals /100 treated) & rare in cattle (1-10 animals/10,000 treated) Loss of appetite & hypersensitivity – very rare in cattle & sheep (<1 animal/10,000 treated)	Adverse events - Injection site reaction, Injection site erythema, Injection site nodule, hyperthermia - very common in cattle & sheep (>1 animal / 10 treated). Injection site abscess – rare in cattle & sheep (1-10 animals/10,000 treated) Abortion, perinatal mortality, premature parturition, Apathy, recumbency, fever, anorexia, lethargy – rare in sheep (1-10 /10,000 and very rare in cattle (<1 animal/10,000 treated. Milk production decrease, Paralysis, ataxia, blindness, incoordination, Pulmonary congestion, dyspnoea, Rumen atony, bloated – very rare in sheep & cattle (<1 animal/ 10,000 treated)
Withdrawal	Zero days	Zero days	Zero days
Shelf life	24 months as packaged 10 hours after first opening packaging	18 months as packaged 10 hours after first opening packaging	2 years as packaged 10 hours after opening immediate packaging
Storage 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 and 252 ml	Box containing vials of 80ml or 200ml

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

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 BTV3 - information for vets - Ruminant Health & Welfare (ruminanthw.org.uk).

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 guidance for vets 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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