

Annex A

EU (MA) number	Invented name	Strength	Pharmaceutical form	Target species	Route of administration	Packaging	Content	Package size	Withdrawal period
EU/2/18/231/001	Syvazul BTV	BTV-1 ^{***}	Suspension for injection	Cattle and Sheep	Intramuscular use, Subcutaneous use	Vial (PP)	80 ml (40 sheep doses or 20 cattle doses)	1 vial	Zero days
EU/2/18/231/002	Syvazul BTV	BTV-1 ^{***}	Suspension for injection	Cattle and Sheep	Intramuscular use, Subcutaneous use	Vial (PP)	200 ml (100 sheep doses or 50 cattle doses)	1 vial	Zero days
EU/2/18/231/003	Syvazul BTV	BTV-4 ^{***}	Suspension for injection	Cattle and Sheep	Intramuscular use, Subcutaneous use	Vial (PP)	80 ml (40 sheep doses or 20 cattle doses)	1 vial	Zero days
EU/2/18/231/004	Syvazul BTV	BTV-4 ^{***}	Suspension for injection	Cattle and Sheep	Intramuscular use, Subcutaneous use	Vial (PP)	200 ml (100 sheep doses or 50 cattle doses)	1 vial	Zero days
EU/2/18/231/005	Syvazul BTV	BTV-8 ^{***}	Suspension for injection	Cattle and Sheep	Intramuscular use, Subcutaneous use	Vial (PP)	80 ml (40 sheep doses or 20 cattle doses)	1 vial	Zero days

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EU/2/18/231/006	Syvazul BTV	BTV-8 ^{mg/ml}	Suspension for injection	Cattle and Sheep	Intramuscular use, Subcutaneous use	Vial (PP)	200 ml (100 sheep doses or 50 cattle doses)	1 vial	Zero days
EU/2/18/231/007	Syvazul BTV	BTV-1 ^{mg/ml} BTV-4 ^{mg/ml}	Suspension for injection	Cattle and Sheep	Intramuscular use, Subcutaneous use	Vial (PP)	80 ml (40 sheep doses or 20 cattle doses)	1 vial	Zero days
EU/2/18/231/008	Syvazul BTV	BTV-1 ^{mg/ml} BTV-4 ^{mg/ml}	Suspension for injection	Cattle and Sheep	Intramuscular use, Subcutaneous use	Vial (PP)	200 ml (100 sheep doses or 50 cattle doses)	1 vial	Zero days
EU/2/18/231/009	Syvazul BTV	BTV-1 ^{mg/ml} BTV-8 ^{mg/ml}	Suspension for injection	Cattle and Sheep	Intramuscular use, Subcutaneous use	Vial (PP)	80 ml (40 sheep doses or 20 cattle doses)	1 vial	Zero days
EU/2/18/231/010	Syvazul BTV	BTV-1 ^{mg/ml} BTV-8 ^{mg/ml}	Suspension for injection	Cattle and Sheep	Intramuscular use, Subcutaneous use	Vial (PP)	200 ml (100 sheep doses or 50 cattle doses)	1 vial	Zero days
EU/2/18/231/011	Syvazul BTV	BTV-4 ^{mg/ml} BTV-8 ^{mg/ml}	Suspension for injection	Cattle and Sheep	Intramuscular use, Subcutaneous use	Vial (PP)	80 ml (40 sheep doses or 20 cattle doses)	1 vial	Zero days

EU (MA) number	Invented name	Strength	Pharmaceutical form	Target species	Route of administration	Packaging	Content	Package size	Withdrawal period
EU/2/18/231/012	Syvazul BTV	BTV-4 ⁻⁻¹ BTV-8 ⁻⁻¹	Suspension for injection	Cattle and Sheep	Intramuscular use, Subcutaneous use	Vial (PP)	200 ml (100 sheep doses or 50 cattle doses)	1 vial	Zero days

--1 Inactivated bluetongue virus, serotype 1 (BTV-1), strain ALG2006/01 E1 RP* \geq 1

Inactivated bluetongue virus, serotype 4 (BTV-4), strain BTV-4/SPA-1/2004 RP* \geq 1

Inactivated bluetongue virus, serotype 8 (BTV-8), strain BEL2006/01 RP* \geq 1

*Relative potency measured by ELISA in relation to a reference vaccine whose efficacy has been demonstrated by challenge in the target species.