

<u>EU Number</u>	<u>Invented Name</u>	<u>Strength</u>	<u>Pharmaceutical Form</u>	<u>Target species</u>	<u>Route of administration</u>	<u>Packaging</u>	<u>Content</u>	<u>Package size</u>	<u>Withdrawal period</u>
EU/2/11/120/001	ZULVAC 1+8 Ovis	Inactivated Bluetongue Virus, serotype 1, strain BTV-1/ALG2006/01 E1 RP* ≥ 1 Inactivated Bluetongue Virus, serotype 8, strain BTV-8/BEL2006/02 RP* ≥ 1	Suspension for injection	Sheep	Subcutaneous use	High Density Polyethylene vials with chlorobutyl stopper and aluminium seal	20ml (10doses)	1 vial	Zero days
EU/2/11/120/002	ZULVAC 1+8 Ovis	Inactivated Bluetongue Virus, serotype 1, strain BTV-1/ALG2006/01 E1 RP* ≥ 1 Inactivated Bluetongue Virus, serotype 8, strain BTV-8/BEL2006/02 RP* ≥ 1	Suspension for injection	Sheep	Subcutaneous use	High Density Polyethylene vials with chlorobutyl stopper and aluminium seal	100ml (50doses)	1 vial	Zero days
EU/2/11/120/003	ZULVAC 1+8 Ovis	Inactivated Bluetongue Virus, serotype 1, strain BTV-1/ALG2006/01 E1 RP* ≥ 1 Inactivated Bluetongue Virus, serotype 8, strain BTV-8/BEL2006/02 RP* ≥ 1	Suspension for injection	Sheep	Subcutaneous use	High Density Polyethylene vials with chlorobutyl stopper and aluminium seal	240ml (120 doses)	1 vial	Zero days

*Relative Potency by a mice potency test compared to a reference vaccine that was shown efficacious in sheep.