

EU Number	Invented Name	Strength	Pharmaceutical Form	Target species	Route of administration	Packaging	Content	Package size	Withdrawal period
EU/2/12/139/001	ZULVAC 1+8 Bovis	Inactivated Bluetongue Virus, serotype 1, strain BTV-1/ALG2006/01 E1 RP* $\geq$ 1 Inactivated Bluetongue Virus, serotype 8, strain BTV-8/BEL2006/02 RP* $\geq$ 1	suspension for injection	Cattle	Intramuscular use	High Density Polyethylene (HDPE) vial with chlorobutyl elastomer rubber stopper and aluminum seal	20 ml (10 doses).	1 vial	Zero days
EU/2/12/139/002	ZULVAC 1+8 Bovis	Inactivated Bluetongue Virus, serotype 1, strain BTV-1/ALG2006/01 E1 RP* $\geq$ 1 Inactivated Bluetongue Virus, serotype 8, strain BTV-8/BEL2006/02 RP* $\geq$ 1	suspension for injection	Cattle	Intramuscular use	High Density Polyethylene (HDPE) vial with chlorobutyl elastomer rubber stopper and aluminum seal	100 ml (50 doses).	1 vial	Zero days
EU/2/12/139/003	ZULVAC 1+8 Bovis	Inactivated Bluetongue Virus, serotype 1, strain BTV-1/ALG2006/01 E1 RP* $\geq$ 1 Inactivated Bluetongue Virus, serotype 8, strain BTV-8/BEL2006/02 RP* $\geq$ 1	suspension for injection	Cattle	Intramuscular use	High Density Polyethylene (HDPE) vial with chlorobutyl elastomer rubber stopper and aluminum seal	240 ml (120 doses).	1 vial	Zero days

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