

Annex A

EU (MA) number	Invented name	Strength	Pharmaceutical form	Target species	Route of administration	Packaging	Content	Package size	Withdrawal period
EU/2/14/176/001	Bovela	--1	Lyophilisate and solvent for suspension for injection	Cattle	Intramuscular use	Lyophilisate: vial (glass); Solvent: bottle (HDPE)	Lyophilisate: 5 doses, solvent: 10 ml	Lyophilisate: 1 vial; solvent: 1 bottle	Zero days.
EU/2/14/176/002	Bovela	--1	Lyophilisate and solvent for suspension for injection	Cattle	Intramuscular use	Lyophilisate: vial (glass); Solvent: bottle (HDPE)	Lyophilisate: 5 doses, solvent: 10 ml	Lyophilisate: 4 vials; solvent: 4 bottles	Zero days.
EU/2/14/176/003	Bovela	--1	Lyophilisate and solvent for suspension for injection	Cattle	Intramuscular use	Lyophilisate: vial (glass); Solvent: bottle (HDPE)	Lyophilisate: 5 doses, solvent: 10 ml	Lyophilisate: 6 vials; solvent: 6 bottles	Zero days.
EU/2/14/176/004	Bovela	--1	Lyophilisate and solvent for suspension for injection	Cattle	Intramuscular use	Lyophilisate: vial (glass); Solvent: bottle (HDPE)	Lyophilisate: 5 doses, solvent: 10 ml	Lyophilisate: 10 vials; solvent: 10 bottles	Zero days.
EU/2/14/176/005	Bovela	--1	Lyophilisate and solvent for suspension for injection	Cattle	Intramuscular use	Lyophilisate: vial (glass); Solvent: bottle (HDPE)	Lyophilisate: 10 doses, solvent: 20 ml	Lyophilisate: 1 vial; solvent: 1 bottle	Zero days.
EU/2/14/176/006	Bovela	--1	Lyophilisate and solvent for suspension for injection	Cattle	Intramuscular use	Lyophilisate: vial (glass); Solvent: bottle (HDPE)	Lyophilisate: 10 doses, solvent: 20 ml	Lyophilisate: 4 vials; solvent: 4 bottles	Zero days.
EU/2/14/176/007	Bovela	--1	Lyophilisate and solvent for suspension for injection	Cattle	Intramuscular use	Lyophilisate: vial (glass); Solvent: bottle (HDPE)	Lyophilisate: 10 doses, solvent: 20 ml	Lyophilisate: 6 vials; solvent: 6 bottles	Zero days.

EU (MA) number	Invented name	Strength	Pharmaceutical form	Target species	Route of administration	Packaging	Content	Package size	Withdrawal period
EU/2/14/176/008	Bovela	--1	Lyophilisate and solvent for suspension for injection	Cattle	Intramuscular use	Lyophilisate: vial (glass); Solvent: bottle (HDPE)	Lyophilisate: 10 doses, solvent: 20 ml	Lyophilisate: 10 vials; solvent: 10 bottles	Zero days.
EU/2/14/176/009	Bovela	--1	Lyophilisate and solvent for suspension for injection	Cattle	Intramuscular use	Lyophilisate: vial (glass); Solvent: bottle (HDPE)	Lyophilisate: 25 doses, solvent: 50 ml	Lyophilisate: 1 vial; solvent: 1 bottle	Zero days.
EU/2/14/176/010	Bovela	--1	Lyophilisate and solvent for suspension for injection	Cattle	Intramuscular use	Lyophilisate: vial (glass); Solvent: bottle (HDPE)	Lyophilisate: 25 doses, solvent: 50 ml	Lyophilisate: 4 vials; solvent: 4 bottles	Zero days.
EU/2/14/176/011	Bovela	--1	Lyophilisate and solvent for suspension for injection	Cattle	Intramuscular use	Lyophilisate: vial (glass); Solvent: bottle (HDPE)	Lyophilisate: 25 doses, solvent: 50 ml	Lyophilisate: 6 vials; solvent: 6 bottles	Zero days.
EU/2/14/176/012	Bovela	--1	Lyophilisate and solvent for suspension for injection	Cattle	Intramuscular use	Lyophilisate: vial (glass); Solvent: bottle (HDPE)	Lyophilisate: 25 doses, solvent: 50 ml	Lyophilisate: 10 vials; solvent: 10 bottles	Zero days.
EU/2/14/176/013	Bovela	--1	Lyophilisate and solvent for suspension for injection	Cattle	Intramuscular use	Lyophilisate: vial (glass); Solvent: bottle (HDPE)	Lyophilisate: 50 doses, solvent: 100 ml	Lyophilisate: 1 vials; solvent: 1 bottle	Zero days.
EU/2/14/176/014	Bovela	--1	Lyophilisate and solvent for suspension for injection	Cattle	Intramuscular use	Lyophilisate: vial (glass); Solvent: bottle (HDPE)	Lyophilisate: 50 doses, solvent: 100 ml	Lyophilisate: 4 vials; solvent: 4 bottles	Zero days.
EU/2/14/176/015	Bovela	--1	Lyophilisate and solvent for suspension for injection	Cattle	Intramuscular use	Lyophilisate: vial (glass); Solvent: bottle (HDPE)	Lyophilisate: 50 doses, solvent: 100 ml	Lyophilisate: 6 vials; solvent: 6 bottles	Zero days.

EU (MA) number	Invented name	Strength	Pharmaceutical form	Target species	Route of administration	Packaging	Content	Package size	Withdrawal period
EU/2/14/176/016	Bovela	--1	Lyophilisate and solvent for suspension for injection	Cattle	Intramuscular use	Lyophilisate: vial (glass); Solvent: bottle (HDPE)	Lyophilisate: 50 doses, solvent: 100 ml	Lyophilisate: 10 vials; solvent: 10 bottles	Zero days.

--1 Modified live bovine viral diarrhoea virus type 1, non-cytopathic parent strain KE-9: $10^{4.0}$ – $10^{6.0}$ TCID₅₀*,
Modified live bovine viral diarrhoea virus type 2, non-cytopathic parent strain NY-93: $10^{4.0}$ – $10^{6.0}$ TCID₅₀*.

** Tissue culture infectious dose 50%