

Annex A

EU (MA) number	Invented name	Strength	Pharmaceutical form	Target species	Route of administration	Immediate packaging	Content	Package size	Withdrawal period
EU/2/98/006/001	Nobilis IB4-91	--1	Lyophilisate for ocular use, suspension/use in drinking water	Chickens	In drinking water use, nebulisation use, ocular use	Vial (glass)	1,000 doses	In cardboard box: 1 vial	Zero days
EU/2/98/006/002	Nobilis IB4-91	--1	Lyophilisate for ocular use, suspension/use in drinking water	Chickens	In drinking water use, nebulisation use, ocular use	Vial (glass)	2,500 doses	In cardboard box: 1 vial	Zero days
EU/2/98/006/003	Nobilis IB4-91	--1	Lyophilisate for ocular use, suspension/use in drinking water	Chickens	In drinking water use, nebulisation use, ocular use	Vial (glass)	5,000 doses	In cardboard box: 1 vial	Zero days
EU/2/98/006/004	Nobilis IB4-91	--1	Lyophilisate for ocular use, suspension/use in drinking water	Chickens	In drinking water use, nebulisation use, ocular use	Vial (glass)	10,000 doses	In cardboard box: 1 vial	Zero days
EU/2/98/006/005	Nobilis IB4-91	--1	Lyophilisate for ocular use, suspension/use in drinking water	Chickens	In drinking water use, nebulisation use, ocular use	Vial (glass)	1,000 doses	In cardboard box: 10 vials	Zero days
EU/2/98/006/006	Nobilis IB4-91	--1	Lyophilisate for ocular use, suspension/use in drinking water	Chickens	In drinking water use, nebulisation use, ocular use	Vial (glass)	2,500 doses	In cardboard box: 10 vials	Zero days
EU/2/98/006/007	Nobilis IB4-91	--1	Lyophilisate for ocular use, suspension/use in drinking water	Chickens	In drinking water use, nebulisation use, ocular use	Vial (glass)	5,000 doses	In cardboard box: 10 vials	Zero days
EU/2/98/006/008	Nobilis IB4-91	--1	Lyophilisate for ocular use, suspension/use in drinking water	Chickens	In drinking water use, nebulisation use, ocular use	Vial (glass)	10,000 doses	In cardboard box: 10 vials	Zero days

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EU/2/98/006/009	Nobilis IB4-91	--1	Lyophilisate for ocular use, suspension/use in drinking water	Chickens	In drinking water use, nebulisation use, ocular use	Vial (glass)	500 doses	In cardboard box: 1 vial	Zero days
EU/2/98/006/010	Nobilis IB4-91	--1	Lyophilisate for ocular use, suspension/use in drinking water	Chickens	In drinking water use, nebulisation use, ocular use	Vial (glass)	500 doses	In cardboard box: 10 vials	Zero days
EU/2/98/006/011	Nobilis IB4-91	--1	Lyophilisate for ocular use, suspension/use in drinking water	Chickens	In drinking water use, nebulisation use, ocular use	Cup (alu/PP)	1,000 doses	In cardboard box: 10 cups	Zero days
EU/2/98/006/012	Nobilis IB4-91	--1	Lyophilisate for ocular use, suspension/use in drinking water	Chickens	In drinking water use, nebulisation use, ocular use	Cup (alu/PP)	5,000 doses	In cardboard box: 10 cups	Zero days
EU/2/98/006/013	Nobilis IB4-91	--1	Lyophilisate for ocular use, suspension/use in drinking water	Chickens	In drinking water use, nebulisation use, ocular use	Cup (alu/PP)	10,000 doses	In cardboard box: 10 cups	Zero days
EU/2/98/006/014	Nobilis IB4-91	--1	Lyophilisate for ocular use, suspension/use in drinking water	Chickens	In drinking water use, nebulisation use, ocular use	Cup (alu/PP)	2,500 doses	In cardboard box: 10 cups	Zero days
EU/2/98/006/015	Nobilis IB4-91	--1	Lyophilisate for ocular use, suspension/use in drinking water	Chickens	In drinking water use, nebulisation use, ocular use	Cup (alu/PP)	1,000 doses	In plastic box: 12 cups	Zero days
EU/2/98/006/016	Nobilis IB4-91	--1	Lyophilisate for ocular use, suspension/use in drinking water	Chickens	In drinking water use, nebulisation use, ocular use	Cup (alu/PP)	2,500 doses	In plastic box: 12 cups	Zero days
EU/2/98/006/017	Nobilis IB4-91	--1	Lyophilisate for ocular use, suspension/use in drinking water	Chickens	In drinking water use, nebulisation use, ocular use	Cup (alu/PP)	5,000 doses	In plastic box: 12 cups	Zero days

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EU/2/98/006/018	Nobilis IB4-91	--1	Lyophilisate for ocular use, suspension/use in drinking water	Chickens	In drinking water use, nebulisation use, ocular use	Cup (alu/PP)	10,000 doses	In plastic box: 12 cups	Zero days

--1 Live attenuated avian infectious bronchitis virus (IBV), variant strain 4-91: $\geq 3.6 \log_{10} \text{EID}_{50}^*$ per dose

* EID_{50} : 50% embryo infective dose - the virus titre required to produce infection in 50% of the embryos inoculated.