Annex I

List of the names, pharmaceutical forms, strengths of the veterinary medicinal products, animal species, routes of administration and marketing authorisation holders in the Member States

Annex IA

List of authorised veterinary medicinal products recommended for variation of the marketing authorisations

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Austria	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E, Injektionslösung für Rind, Pferd, Schwein und Hund	Retinolpalmitat All-rac alpha tocopherolacetat Colecalciferol	176,47 mg (300 000 IU) 50 mg 2,5 mg (100 000 IU)	Solution for injection	Cattle, horses, pigs, dogs	For intramuscular and subcutaneous use
Austria	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Vitasol AD3E Injektionslösung für Tiere	Vitamin A als Retinol Palmitat Vitamin D3 als colecalciferol Vitamin E als all-rac-α-tocopherolacetat	50 000 I.E. 25 000 I.E. 20 mg	Solution for injection	Cattle, horses, pigs, dogs	For subcutaneous, intramuscular, in large animals also intravenous (slow, body warm) injection
Austria	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Vitasol AD3EC - Injektionslösung für Tiere	Vitamin A als Retinol Palmitat Vitamin D3 als Colecalciferol all-rac-α-Tocopherolacetat (Vit. E) Ascorbinsäure (Vit. C)	50 000 I.E. 25 000 I.E. 30 mg 100 mg	Solution for injection	Cattle, horses, pigs, dogs	For intramuscular and subcutaneous use
Belgium	Zoetis Belgium s.a. Rue Laid Burniat, 1 B-1348 Louvain-La-Neuve Belgium	Duphafral AD3E	Vitamin A Vitamin D3 Vitamin E	500 000 IU 50 000 IU 50 mg	Solution for injection	Cattle, horses, sheep, pigs	For intramuscular use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Belgium	V.M.D. n.v. Hoge Mauw 900 B-2370 Arendonk Belgium	Vitamine A+D3+E	Vitaminum A Colecalciferolum Alphatocopheroli acetas	50 000 IU 25 000 IU 20 mg	Solution for injection	Calf, sow, piglets	For intramuscular use
Bulgaria	Asklep-Pharma Ltd Lyulin 7, bl. 711A, shop 3 Sofia Bulgaria	Norovit	Vitamin A palmitate, Cholecalciferol (Vitamin D3), Vitamin E acetate, Thiamine hydrochloride (Vitamin B1), Riboflavin sodium phosphate (Vitamin B2), Pyridoxine hydrochloride (Vitamin B6), Nicotinamide, Dexpanthenol, Cyanocobalamin (Vitamin B12)	15 000 IU 25 µg 20 mg 10 mg 5 mg 3 mg 35 mg 25 mg 25 µg	Solution for injection	Cattle, horses, pigs, sheep	For intramuscular and subcutaneous use
Bulgaria	Biovet JSC 39, Petar Racov Str. 4550 Peshtera Bulgaria	Vialiton solution for injection	Vitamin A; Vitamin D3; Vitamin E	20 mg/ml (50 000 IU) 0,625 mg/ml (25 000 IU) 20 mg/ml	Solution for injection	Cattle, calves, chickens, horses, pigs, dogs, cats	For intramuscular, subcutaneous and oral use
Bulgaria	Vetprom AD 26, Otez Paissij Str. 2400 Radomir Bulgaria	Vitamin AD3E solutio pro injectionibus	Vitamin A, Cholecalciferol, Alpha – Tocopheryl Acetate (Vit. E)	1 500 000 IU/100 ml 2 000 000 IU/100 ml 1 g/100 ml	Solution for injection	Cattle, sheep, goats, horses, pigs, piglets	For intramuscular, subcutaneous and oral use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Bulgaria	Provet S. A. 77, Posidonos Avenue 174 55 Alimos, Attiki Greece	Zingul inj.	Vitamin A (as palmitat); Vitamin D3; Vitamin E (as acetat)	50 000 IU/ml 25 000 IU/ml 50 mg/ml	Solution for injection	Cattle, goats, horses, pigs, sheep	For intramuscular use
Croatia	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E pro injectione, otopina za injekciju, za konje, goveda, svinje i pse	Retinol (vitamin A) palmitate, All-rac alpha tocopheryl acetate Cholecalciferol	176,47 mg (300 000 IU) 50 mg 100 mg	Solution for injection	Cattle, pigs, horses, dogs	For intramuscular and subcutaneous use
Croatia	Krka - Farma d.o.o. Radnička cesta 48 10000 Zagreb Croatia	Vitamin AD3E, emulzija za injekciju, goveda, ovce, koze, konji, svinje, kunići, psi, mačke	Vitamin A (retinol) palmitate, cholecalciferol and all-rac-α-Tocopheryl acetate	50 000 IU/ml 25 000 IU/ml 20 mg/ml	Emulsion for injection	Cattle, sheep, goats, horses, pigs, rabbits, dogs, cats	For intramuscular and subcutaneous use
Cyprus	Fatro S.p.A. Via Emilia 285 40064 Ozzano dell'Emilia Bologna Italy	Adecon injection Ενέσιμο διάλυμα για βοοειδή, άλογα, χοίρους, πρόβατα και αίγες	Retinol acetate (Vitamin A) Vitamin D3 Vitamin E	100 000 IU /ml 25 000 IU /ml 100 mg/ml	Solution for injection	Cattle, horses, pigs, sheep, goats	Intramuscular (may be administered orally)

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Cyprus	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Belavit AD3E, ενέσιμο διάλυμα για άλογα, βοοειδή, χοίρους και σκύλους	Retinol palmitate Vitamin D3 Vitamin E acetate	176,47 mg 100 mg per ml 50 mg per ml	Solution for injection	Cattle, pigs, horses, dogs	For subcutaneous or intramuscular use
Czech Republic	Kela NV Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Adedri-kel injekční roztok	Retinol+ Colecalciferol	100 000 IU + 50 000 IU	Solution for injection	Horses, cattle, pigs, sheep, goats, dogs, cats	For intramuscular and subcutaneous use
Czech Republic	Bioveta, a. s. Komenského 212 683 23 Ivanovice na Hané Czech Republic	ADE – vit injekční roztok	Retinol+ Tocopherol+ Ergocalciferol	1 ml: 100 000 IU + 30 mg + 100 000 IU	Solution for injection	Cattle, dogs, goats, horses, pigs, rabbits, sheep	For intramuscular use
Czech Republic	Pharmagal Ltd. Murgašova 5, 949 01 Nitra Slovak Republic	Triavit injekční roztok	Retinol+ Tocopherol+ Colecalciferol	1 ml: 100 000 IU 50 mg 50 000 IU	Solution for injection	Horses, cattle, pigs, sheep, dogs, rabbits, poultry	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Czech Republic	Alfasan International B.V. Kuipersweg 9 Woerden Utrecht The Netherlands	Vitamin AD3E Alfasan injekční roztok	Retinol+ Tocopherol+ Colecalciferol	1 ml: 300 000 IU 50 mg 100 000 IU	Solution for injection	Cattle, goats, horses, pigs, sheep	For intramuscular and subcutaneous use
Estonia	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E bela-pharm	Retinol+ Tocopherol+ Colecalciferol	1ml: 300 000 IU (176,47 mg) 50 mg 100 000 IU (100 mg)	Solution for injection	Cattle, pigs, horses, dogs	For intramuscular and subcutaneous use
Estonia	Alfasan International B.V. Kuipersweg 9 Woerden Utrecht The Netherlands	Vitamin AD3E forte	Retinol+ Tocopherol+ Colecalciferol	1ml: 500 000 IU+ 50 mg+ 75 000 IU	Solution for injection	Cattle, cats, dogs, goats, horses, sheep	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Estonia	Interchemie Werken De Adelaar Eesti AS Vanapere tee 14, Püünsi küla Viimsi vald, Harju maakond 74013 Estonia	Vitol-140	Retinol+ Tocopherol+ Colecalciferol	1 ml: 80 000 IU+ 20 mg+ 40 000 IU	Solution for injection	Cattle, horses, pigs, sheep	For intramuscular use
France	Virbac 1ere Avenue 2065 M - L.I.D. 06516 Carros Cedex France	Ad-Ject	Retinol palmitate, Cholecalciferol, Alpha-tocopherol (as acetate)	500 000 IU/ml 75 000 IU/ml 45,6 mg/ml	Solution for injection	Cattle, sheep, pigs	For intramuscular use
France	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Belavit AD3E Solution for injection for horses, cattle, pigs and dogs	Retinol palmitate, Cholecalciferol concentrate (oily form), All-rac-alpha-tocopheryl acetate	176,47 mg/ml 100 mg/ml 50 mg/ml	Solution for injection	Cattle, pigs, horses, dogs	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
France	Dopharma France 23, Rue du Prieuré Saint Herblon 44150 Vair sur Loire France	Cofavit 500	Retinol (as propionate), Cholecalciferol, Alpha-tocopherol (as acetate)	500 000 IU/ml 75 000 IU/ml 45,55 mg/ml	Solution for injection	Cattle, sheep, goats, pigs, rabbits	For intramuscular and subcutaneous use
France	Laboratoires Biové 3 Rue de Lorraine 62510 Arques France	Trivitase	Retinol palmitate, Cholecalciferol, Alpha-tocopherol (as acetate)	500 000 IU/ml 75 000 IU/ml 50 mg/ml	Solution for injection	Cattle, sheep, goats, pigs	For intramuscular use
Germany	Serumwerk Bernburg AG Hallesche Landstrasse 105b 06406 Bernburg Germany	Ursovit AD_3EC, wässrig pro inj.	Retinol palmitate Colecalciferol Alpha-tocopherol acetate Ascorbic acid	1 ml: 30 mg (50 000 IU) 0,125 mg 30 mg 100 mg	Solution for injection	Cattle, cats, horses, minks, pigs, sheep, goats, rabbits, dogs	For intramuscular and subcutaneous use
Germany	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E pro injectione	Retinol palmitate (Vitamin A) All-rac alpha tocopheryl acetate Cholecalciferol	176,47 mg (300 000 IU) 50 mg 100 mg	Solution for injection	Cattle, pigs, horses, dogs	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Germany	AniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Vitamin ADE aniMedica	Retinol palmitate (Vitamin A) Colecalciferol All-rac-alpha-Tocopherolacetat	176,47 mg (300 000 IU) 2,5 mg 50 mg	Solution for injection	Cattle, pigs, sheep, goats, horses, dogs	For intramuscular use
Greece	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Belavit AD3E, solution for injection for horses, cattle, pigs, and dogs	Vitamin A Vitamin D3 Vitamin E acetate	176,47 mg/ml 100 mg/ml 50 mg/ml	Solution for injection	Cattle, pigs, horses, dogs	For intramuscular and subcutaneous use
Greece	A.Nikolakopoulos A.E, 115 Galatsiou Avenue, Galatsi 11146 Athens Greece	Bremervit AD3E	Vitamin A Vitamin D3 Vitamin E acetate	(300 000 IU+100 000 IU+50 mg)/ml	Solution for injection	Cattle, horses, pregnant sow, calves, foals, pigs, sheep, goats, piglets, lambs	For intramuscular use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Greece	Erfar SA Altani & Mikras Asias 2 St., 15351 Pallini Attikis Athens Greece	Adepur	Vitamin A Vitamin D3 Vitamin E acetate	(50 000 IU + 25 000 IU + 20 mg)/ml	Solution for injection	Cattle, horses, pigs, sheep, goats, calves, lambs, piglets	For intramuscular use
Greece	Hellafarm AE 1st km Paiania-Markopoulou Avenue 19002 Paiania Attiki Athens Greece	Labiasol AD3E-500	Vitamin A Propionate Vitamin D3 Vitamin E	(500 000 IU + 75 000 IU+ 50 IU)/ml	Suspension for injection	Cattle, goats, sheep, pigs, horses	For intramuscular use
Greece	Intervet Hellas S.A. 63, Agiou Dimitriou str, GR-174 56 Alimos, Athens Greece	Turlin AD3E	Vitamin A Palmitate Vitamin D3 Vitamin E	(50 000 IU + 25 000 IU + 20 mg)/ml	Solution for injection	Cattle, horses, pigs, goats, sheep, poultry	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Greece	Hellafarm AE 1st km Paiania-Markopoulou Avenue 19002 Paiania Attiki Athens Greece	Vitamin AD3E/New Vet	Vitamin A Palmitate Vitamin D3 Vitamin E	(50 000 IU+ 25 000 IU+ 20 mg)/ml	Solution for injection	Cattle, calves, pigs, horses, sheep, goats, piglets	For intramuscular use
Greece	Eurovet Animal Health B.V. Handelsweg 25 5531 AE Bladel The Netherlands	Vitamine AD3E/Eurovet	Vitamin A Palmitate Vitamin D3 Vitamin E	(80 000 IU + 40 000 IU + 20 mg)/ml	Solution for injection	Cattle, horses, sheep, goats, pigs, dogs, cats	For intramuscular and subcutaneous use
Greece	Anafasis LTD 3 Santorinis St, Pallouriotissa 1048 Nicosia Cyprus	Vitamins AD3E/Anafasis	Vitamin A palmitate Vitamin D3 Vitamin E	(50 000 IU + 25 000 IU + 20 mg)/ml	Solution for injection	Cattle, horses, pigs, sheep, goats	For intramuscular, intravenous use
Greece	Anafasis LTD 3 Santorinis St, Pallouriotissa 1048 Nicosia Cyprus	Vitamins AD3E/Anafasis	Vitamin A palmitate Vitamin D3 Vitamin E	(300 000 IU+100 000 IU +50 mg)/ml	Solution for injection	Cattle, horses, pigs, sheep, goats, dogs	For intramuscular, intravenous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Greece	Provet S. A. 77 Posidonos Avenue 174 55 Alimos Attiki Greece	Zingul	Vitamin A (as palmitate) Vitamin D3 Vitamin E	(50 000 IU+ 25 000 IU + 50 mg)/ml	Solution for injection	Cattle, horses, pigs, sheep, goats	For intramuscular use
Hungary	Kela NV Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Neovit AD3E injekció A.U.V.	Vitamin A, cholecalciferol, alpha tocopherol acetate	100 000 IU/ml 50 000 IU/ml 5 mg/ml	Solution for injection	Cattle, cats, dogs, goats, horses, pigs, sheep	For intramuscular and subcutaneous use
Hungary	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Belavit AD3E 176,47/2,5/50 mg/ml oldatos injekció lovak, szarvasmarhák, sertések, kutyák számára A.U.V.	Vitamin A, vitamin D3, vitamin E	300 000 IU/ml 100 000 IU/ml 50 mg/ml	Solution for injection	Cattle, pigs, horses, dogs	For intramuscular and subcutaneous use
Hungary	Bio-Vet Kft. 4487 Tiszatelek, Kossuth u. 151. Hungary	Ferriade injekció A.U.V.	Iron-dextran, vitamin A, vitamin D3, vitamin E	100 mg/ml 10 000 IU/ml 1 000 IU/ml 10 mg/ml	Solution for injection	Calves, lambs, piglets	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Hungary	UNIVET Ltd. Tullyvin, Cootehill, Co. Cavan, Ireland	Multivitamines oldatos injekció A.U.V.	Vitamin A, vitamin B1, B2, B6, B12, D3, E, nicotinamide, D-panthenol	1 ml: 15 000 IU 10 mg 5 mg 3 mg 50 µg 1 000 IU 10 mg 35 mg 25 mg	Solution for injection	Cattle, pigs	For intramuscular use
Hungary	Bremer Pharma GmbH Werkstrasse 42, 34414 Warburg, Germany	Vitamin AD3E injekció A.U.V.	Vitamin A, cholecalciferol, vitamin E	50 000 IU/ml, 25 000 IU/ml, 20 mg/ml	Solution for injection	Horses, cattle, pigs, dogs, cats	For intramuscular use
Iceland	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E pro injectione	Retinol Palmitate, Colecalciferolum INN, all-rac-alpha-Tocopheryl Acetate	176,47mg/ml 100 mg/ml 50 mg/ml	Solution for injection	Cattle, pigs, horses, dogs	For intramuscular and subcutaneous use
Ireland	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Belavit AD3E, solution for injection for horses, cattle, pigs, and dogs	Retinol palmitate (Vitamin A) Vitamin D3 Vitamin E acetate	176,47 mg/ml (300 000 IU) 100 mg/ml 50 mg/ml	Solution for injection	Cattle, pigs, horses, dogs	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Ireland	Chem-Pharm, Ballyvaughan, Co. Clare, Ireland	Multivitamin Injection	Vitamin A Palmitate Vitamin D3 (Cholecalciferol) Vitamin E (Alpha tocopheryl acetate) Vitamin B1 (Thiamine hydrochloride) Vitamin B2 (Riboflavin Sodium Phosphate) Vitamin B6 (Pyridoxine) Nicotinamide Dexpanthenol Vitamin B12 (Cyanocobalamin)	1 ml: 15 000 IU 25 µg 20 mg 10 mg 5 mg 3 mg 35 mg 25 mg 25 µg	Solution for injection	Cattle, sheep, pigs	For intramuscular and subcutaneous use
Italy	Ceva Salute Animale S.p.A. Viale Colleoni 15 20864 Agrate Brianza (MB) Italy	Fosforilene Plus, soluzione iniettabile per vitelli, equini, suini, agnelli	Phosphorylcholamine retinol palmitate d, l-alpha-tocopheryl acetate sodium selenite	40 mg/ml 10 000 IU/ml 30 mg/ml 0,4 mg/ml	Solution for injection	Calves, horses, pigs, lambs	For intramuscular use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	Fatro S.p.A. Via Emilia 285 40064 Ozzano dell'Emilia Bologna Italy	Adecon, soluzione iniettabile per bovini, equini, suini, ovi-caprini	Retinol acetate (vitamin A) cholecalciferol (vitamin D3) alpha-tocopherol equal to alpha-tocopherol acetate (vitamin E)	100 000 IU/ml; 25 000 IU/ml; 100 mg/ml	Solution for injection	Cattle, horses, pigs, sheep, goats	For intramuscular use (may be administered orally)
Italy	Ceva Salute Animale S.p.A. Viale Colleoni 15 20864 Agrate Brianza (MB) Italy	Adisole A-D-E, soluzione iniettabile per bovini, suini, ovini, equini	Vitamin A palmitate vitamin D 3 vitamin E acetate	100 000 IU/ml 25 000 IU/ml 100 mg/ml	Solution for injection	Cattle, pigs, sheep, horses	For intramuscular use
Italy	Fatro S.p.A. Via Emilia 285 40064 Ozzano dell'Emilia Bologna Italy	Idrade, emulsione iniettabile per bovini, equini, suini, ovini	Retinol propionate (vit. A) cholecalciferol (vit. D3) d, l-alpha tocopherol acetate (vit. E)	500 000 IU 75 000 IU 50 mg	Emulsion for injection	Cattle, horses, pigs, sheep	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Italy	Izo S.r.l. a socio unico Via San Zeno 99/A 25124 Brescia Italy	Izotrevit, soluzione iniettabile per bovini, ovini e suini	Retinol Ergocalciferol d-l-α-tocopherol	500 000 IU/ml 75 000 IU/ml 50 IU/ml	Solution for injection	Cattle, pigs, sheep	For deep intramuscular or intraruminal use: cattle Intramuscular use: pigs Subcutaneous use: sheep subcutaneously
Italy	Labiana Life Sciences S.A. Venus, 26 Terrassa 08228 Barcelona Spain	Labhidro AD3E 100 N	Retinol acetate (vitamin A) cholecalciferol (vitamin D3) d-l alpha-tocopheril acetate (vitamin E)	10 000 000 IU/100 ml 5 000 000 IU/100 ml 10 g/100 ml	Solution for injection	Cattle, pigs, sheep, goats, horses	For intramuscular use
Italy	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E pro injectione, soluzione iniettabile per equini, bovini, suini e cani	Retinol palmitate (Vitamin A) all-rac alpha tocopheryl acetate (Vitamin E) Cholecalciferol (Vitamin D)	176,47 mg (300 000 IU) 50 mg 2,5 mg (100 000 IU)	Solution for injection	Cattle, pigs, horses, dogs	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Latvia	Krka, d.d., Novo mesto Šmarješka cesta 6 8501 Novo mesto Slovenia	Vitamin AD3E Krka injection emulsija injekcijām liellopiem, zirgiem, cūkām, aitām, kazām, trušiem, suņiem un kaķiem	Retinyl palmitate (Vitamin A); Cholecalciferol (vitamin D3); Tocopheryl acetate (vitamin E)	50 000 IU/ml 25 000 IU/ml 20 mg/ml	Emulsion for injection	Cattle, horses, pigs, sheep, goats, rabbits, dogs, cats, foals, piglets, calves, goat kids, lambs	For intramuscular and subcutaneous use
Latvia	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E pro injectione šķīdums injekcijām zirgiem, liellopiem, cūkām un suņiem	Retinol palmitate All-rac alpha tocopheryl acetate Oily solution of cholecalciferol 100 mg (contains 2,5 mg cholecalciferol; equivalent to 100 000 IU Vitamin D3)	176,47 mg (300 000 IU) 50 mg 2,5 mg (100 000 IU)	Solution for injection	Cattle, pigs, horses, dogs	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Latvia	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Vitasol AD3EC šķīdums injekcijām zirgiem, liellopiem, cūkām un suņiem	Vitamin A (retinyl propionate), Vitamin D3 (cholecalciferol), Vitamin E (DL-α-tocopheryl acetate), Vitamin C (ascorbinic acid)	50 000 IU 25 000 IU 30 mg 100 mg	Solution for injection	Horses, cattle, pigs, dogs	For intramuscular and subcutaneous use
Lithuania	UAB Interchemie werken De Adelaar LT Vinčų g. 3-48 46297 Kaunas Lithuania	Introvit, injekcinis tirpalas galvijams, arkliams, ožkoms, avims ir kiaulėms	Vit. A, retinol oil+ vit. D3, cholecalciferol+ vit.E, alpha-tocopherol acetate+vit.B1, thiamine hydrochloride+vit. B2, riboflavin sodium phosphate+vit. B6, pyridoxine hydrochloride+ vit. B12, cyanocobalamin+ dexpanthenol+ nicotinamide+ biotin+ choline chloride+ lysine hydrochloride+ DL-methionine	15 000 IU + 7 500 IU + 20 mg + 10 mg + 5 mg + 3 mg + 60 µg + 25 mg + 50 mg + 125 µg + 12,5 mg + 7 mg + 5 mg	Solution for injection	Cattle, horses, calves, foals, goats, sheep, lambs, pigs	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Lithuania	Bioveta, a. s. Komenského 212 683 23 Ivanovice na Hané Czech Republic	Multivit–Mineral, injekcinis tirpalas	Retinol + cholecalciferol + vitamin E + thiamine + riboflavin + pyridoxine + cyanocobalamin + dexpanthenol + nicotinic acid+ inositol + methionine + choline citrate + magnesium hypophosphite hexahydrate + cobalt chloride + copper sulfate + zinc sulfate	50 000 IU + 25 000 IU + 4 mg + 10 mg + 0,04 mg + 2 mg + 0,01 mg + 2 mg + 5 mg + 2 mg + 5 mg + 5 mg + 1 mg + 0,02 mg + 0,1 mg + 0,1 mg	Solution for injection	Cattle, horses, sheep, pigs, goats, dogs, chickens, turkeys, ducks, geese, pigeons, exotic birds	For intramuscular, subcutaneous and oral use
Lithuania	Krka, d.d., Novo mesto Šmarješka cesta 6 8501 Novo mesto Slovenia	Vitamin AD3E Krka, injekcinė emulsija	Retinol palmitate cholecalciferol α-tocopheryl acetate	50 000 IU/ml 25 000 IU/ml 20 mg/ml	Emulsion for injection	Cattle, horses, pigs, sheep, goats, rabbits, dogs, cats	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Lithuania	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E, injekcinis tirpalas	Retinol palmitate+ Cholecalciferol+ α-tocopheryl acetate	176,47 mg (300 000 IU) 2,5 mg (100 000 IU) 50 mg	Solution for injection	Cattle, calves, pigs, piglets, weaned piglets, horses, dogs	For intramuscular and subcutaneous use
Lithuania	UAB Interchemie werken De Adelaar LT Vinčų g. 3-48 46297 Kaunas Lithuania	Vitol-140, injekcinis tirpalas	Retinol palmitate (vit. A)+ cholecalciferol (vit. D3) + alpha-tocopherol acetate (vit. E)	1 ml: 80 000 IU+ 40 000 IU+ 20 mg	Solution for injection	Cattle, calves, sheep, goats, horses, pigs, dogs, cats	For intramuscular and subcutaneous use
Lithuania	Dopharma B.V. Zalmweg 24 4941 VX Raamsdonksveer The Netherlands	Vitol-Ject Forte, injekcinis tirpalas	Retinol propionate + cholecalciferol + thiamine hydrochloride+ riboflavin sodium phosphate+ pyridoxine hydrochloride+ cyanocobalamin+ ascorbic acid+ α-tocopherol acetate+ D-panthenol+ nicotinamide	50 000 IU+ 25 000 IU+ 2,5 mg+ 2 mg+ 1,25 mg+ 3 µg+ 2 mg+ 4 mg+ 3 mg+ 12,5 mg	Solution for injection	All animals	For intramuscular use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Malta	Fatro S.p.A. Via Emilia 285 40064 Ozzano dell'Emilia Bologna Italy	Adecon, solution for injection for cattle, horses, pigs, sheep and goats	Retinol acetate, Cholecalciferol, α-tocopherol	100 000 IU 25 000 IU 100 mg	Solution for injection	Cattle, goats, horses, pigs, sheep	For Intramuscular use or oral administration
Malta	Interchemie werken "De Adelaar" B.V. Metaalweg 8, 5404 CG Venray The Netherlands	Introvit	Retinol palmitate, cholecalciferol, α-tocopherol acetate, thiamine hydrochloride, riboflavine sodium phosphate, pyridoxine hydrochloride, cyanocobalamin, Dexpanthenol, Nicotinamide, Biotin, Choline chloride, Lysine hydrochloride, DL- Methionine	15 000 IU, 7 500 IU, 20 mg, 10 mg, 5 mg, 3 mg, 60 µg, 25 mg, 50 mg, 125 mcg, 12,5 mg, 7 mg, 5 mg	Solution for injection	Cattle, calves, foals, goats, horses, lambs, pigs, sheep	For intravenous or subcutaneous use
Malta	Labiana Life Sciences S.A Carrer de Venus, 26 08228 Terrassa (Barcelona) Spain	Labhidro AD3E Injectable	Vitamin A, Vitamin D3, Vitamin E (all-rac-α-tocopheryl acetate)	500 000 UI, 75 000 UI, 50 mg	Solution for injection	Cattle, goats, horses, pigs, sheep	For intramuscular use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Malta	Labiana Life Sciences S.A Carrer de Venus, 26 08228 Terrassa (Barcelona) Spain	NOV-A-VIT 500	Vitamin A (retiinol propionate), cholecalciferol, All-rac-α-tocopheryl acetate (Vitamin E)	500 000 IU, 75 000 IU, 50 mg	Emulsion for injection	Cattle, goats, pigs, sheep	For intramuscular use
Malta	Kepro B.V. Maagdenburgstraat 17 7421 ZA Deventer The Netherlands	Vita Flash Inj.	Vitamin A, Vitamin D3, Vitamin E acetate, Vitamin B1 HCl, Vitamin B2 phosphate sodium, Vitamin B3, Vitamin B6 HCl, Vitamin B12, Vitamin C, D-Panthenol	50 000 IU, 25 000 IU, 4 mg, 2,5 mg 2 mg, 12,5 mg, 1,25 mg, 30 µg, 2 mg, 3 mg	Solution for injection	Cattle, calves, foals, goats, horses, lambs, piglets, pigs, sheep	For intramuscular and subcutaneous use
Malta	Interchemie werken ''De Adelaar'' LT, Vincu g. 3-48, Kaunas, Lithuania	Vitol-140	Retinol palmitate, Cholecalciferol, α-tocopherol acetate	80 000 IU, 40 000 IU, 20 mg	Solution for injection	Cattle, calves, sheep, goats, horses, pigs, dogs, cats	For intramuscular or subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Norway	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Belavit AD3E vet	Retinol palmitate Vitamin D3 Vitamin E acetate	176,47 mg (300 000 IU) 100 mg/ml 50 mg/ml	Solution for injection	Cattle, pigs, horses, dogs	For intramuscular and subcutaneous use
Poland	Eurovet Animal Health B.V. Handelsweg 25 5531 AE Bladel The Netherlands	Witamina AD3E 80/40/20 pro.inj.	Vitaminum A Cholekalcyferolum int-rac-alfa-Tocopherylis acetas	(80 000 IU+ 40 000 IU + 20 mg)/ml	Solution for injection	Horses, cattle, pigs, sheep, goats, dogs, cats	For intramuscular use
Portugal	Zoetis Portugal, Lda Lagoas Park Edifício 10, 2740-271 Porto Salvo Portugal	Duphafral Multi	Vitamin A palmitate Cholecalciferol (vitamin D3) a-tocopherol acetate (vitamin E) Thiamine hydrochloride (vitamin B1) Riboflavin (vitamin B2 as sodium phosphate) Pyridoxine hydrochloride (vitamin B6) Cyanocobalamin (vitamin B12) Nicotinamide D-panthenol	15 000 IU 7 500 IU 20 mg 10 mg 5 mg 3 mg 20 µg 35 mg 25 mg	Solution for injection	Cats, dogs, visions Newly born from: cattle, goats, horses, pigs, sheep	For intramuscular use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Portugal	Divasa-Farmavic, S.A. Ctra. Sant Hipòlit, km 71 08503 Gurb - Vic Barcelona Spain	Polivit AD3E Solução Injectável para bovinos, suínos, ovinos, caprinos, equinos, cães e gatos. Vitamina A, Vitamina D3, Vitamina E	Vitamin A Vitamin D3 Vitamin E	500 000 IU/ml 75 000 IU/ml 50 IU/ml	Solution for injection	Cattle, cats, dogs, goats, horses, pigs, sheep	For intramuscular use
Portugal	Vetlima Sociedade Distribuidora de Produtos Agro-Pecuários, S.A. Centro Empresarial da Rainha, Lote 27 2050-501 Vila Nova da Rainha Portugal	Vitalbion solução injetável para bovinos, ovinos e suínos	Vitamin A Vitamin D3 Vitamin E	500 000 IU/ml 75 000 IU/ml 50 mg	Solution for injection	Cattle, pigs, sheep	For intramuscular use
Portugal	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E pro injectione, solução injetável para equídeos, bovinos, suínos e cães	Retinol palmitate Vitamin D3 Vitamin E acetate	176,47 mg/ml (300 000 IU) 100 mg/ml 50 mg/ml	Solution for injection	Cattle, pigs, horses, dogs	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Romania	Interchemie werken "De Adelaar" B.V. Metaalweg 8, 5404 CG Venray The Netherlands	Introvit	Vitamin A (retinol palmitate) Vitamin D3 (cholecalciferol) VitaminE (α- tocoferol acetate) Vitamin B1 (thiamine HCl) Vitamin B2 (Riboflavin sodium fosfate) Vitamin B6 (Pyridoxine HCl) Vitamin B12 (Cyancobalamin) D-panthenol Nicotinamide Folic acid Choline chloride Biotin D,L - methionine L- lysine HCl	15 000 IU 7 500 IU 20 mg 10 mg 5 mg 3 mg 60 µg 25 mg 50 mg 150 µg 12,5 mg 125 µg 5 mg 7 mg	Solution for injection	Cattle, horses, goats, sheep, pigs	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Romania	Dutch Farm International BV, Nieuw Walden 112, 1394 PE Nederhorst den Berg The Netherlands	Multivit inj.	Vitamin A concentrate Oily concentrate cholecalciferol (vitamin D3) Tocoferol acetate (vitamin E) Thiamine HCl (vitamin B1) Riboflavin sodium fosfate (vitamin B2) Pyridoxine HCl (vitamin B6) Cyancobalamin (vitamin B12) Ascorbic acid (vitamin C) Nicotinamide D-panthenol	50 000IU 25 000IU 4 mg 2,5mg 2 mg 1,25 mg 30 µg 2 mg 12,5 mg 3 mg	Solution for injection	Horses, foals, cattle, calves, lambs, piglets, sows, chickens, pigeons	For intramuscular and subcutaneous use
Romania	S.C. Romvac Company S.A. Şos. Centurii, nr. 7 Voluntari Romania	Multivitarom	Choline, Vitamin A Vitamin B1 Vitamin B2 Vitamin B3 Vitamin B5 Vitamin B6 Vitamin C Vitamin D3 Vitamin E, Vitamin B12	0,25 mg/ml, 20 000 IU 0,1 mg/ml 0,08 mg/ml 0,35 mg/ml 0,50 mg/ml 0,10 mg/ml 50 mg/ml 200 IU/ml 8 IU /ml 0,50 mg/ml	Solution for injection	Cattle, horses, goats, sheep, pigs, dogs, cats	For intramuscular use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Romania	S. C. Pasteur - Filiala Filipesti S.A str. Principala, nr.Jud Prahova Romania	Multi-vita-vet	Vitamin A (retinol palmitate) Vitamin D3 (cholecalciferol) Vitamin E (tocoferol acetate) Vitamin B1 (Thiamine HCl) Vitamin B2 (Riboflavin sodium phosphate) Vitamin B3 (Nicotinamide) Vitamin B6 (Pyridoxine HCl) Vitamin B12 (Cyancobalamin) Vitamin B5 (D-panthenol)	1 ml: 15 000 IU 1 100 IU 20 mg 10 mg 7 mg 35 mg 3,5 mg 0,005 mg 25 mg	Solution for injection	Cattle, horses, sheep, goats, pigs, dogs, cats	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Romania	Kepro B.V. Maagdenburgstraat 17 7421 ZA Deventer The Netherlands	Vitaflash	Vitamin A (retinol palmitate) Vitamin B1 HCl (thiamine HCl) Vitamin B2 (riboflavin sodium phosphate) Vitamin B3 (nicotinamide) Vitamin B6 (pyridoxine HCl) Vitamin C (ascorbic acid) Vitamin D3 (cholecalciferol) Vitamin E acetate (α-tocoferol acetate) Vitamin B12 (Cyancobalamine) Vitamin B5 (D-panthenol)	1 ml: 50 000 IU 2,5 mg 2 mg 12,5 mg 1,25 mg 2 mg 25 000 IU 4 mg 30 µg 3 mg	Solution for injection	Cattle, horses, sheep, pigs	For intramuscular and subcutaneous use
Romania	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E	Vitamin A Vitamin D3 Vitamin E	176,47 mg (300 000 IU) 2,50 mg (100 000 IU) 50 mg	Solution for injection	Cattle, pigs, horses, dogs	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Romania	S.C. Romvac Company S.A. Şos. Centurii, nr. 7 Voluntari Romania	Vitamin AD3E	Vitamin A Vitamin D3 Vitamin E	50 000 IU/ml, 5 000 IU/ml, 20 mg/ml	Solution for injection	Cattle, horses, sheep, goats, pigs, poultry, dogs, cats, pigeons	For intramuscular and subcutaneous use
Romania	S. C. Pasteur - Filiala Filipesti S.A str. Principala, nr. Jud Prahova Romania	Vitamina AD3E	Vitamin A (as palmitate) Vitamin D3 (cholecalciferol) Vitamin E (as α-tocopherol acetate)	100 000 IU/ml 10 000 IU/ml 50 IU/ml	Solution for injection	Cattle, horses, goats, rabbits, sheep, pigs, dogs, cats	For intramuscular and subcutaneous use
Romania	Interchemie Werken De Adelaar Eesti AS Vanapere tee 14, Püünsi küla Viimsi vald, Harju maakond 74013 Estonia	Vitol-140	Vitamin A (retinol palmitate) Vitamin D3 (cholecalciferol) Vitamin E (α-tocopherol acetate)	80 000 IU/ml 40 000 IU/ml 20 mg/ml	Solution for injection	Cattle, horses, sheep, goats, pigs, dogs, cats	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Romania	Alapis S.A. 19 300 Aspropyrgos Mailbox 26 Athens Greece	Zingul AD3E	Vitamin A Vitamin D3 Vitamin E	50 000 IU/ml 25 000 IU/ml 50 mg/ml	Solution for injection	Cattle, horses, goats, sheep, pigs	For intramuscular use
Slovak Republic	Bioveta, a. s. Komenského 212 683 23 Ivanovice na Hané Czech Republic	ADE-vit Injekčný roztok	Retinoli propionas-Ergocalciferolum Tocoferoli alfa acetas	1 ml: 100 000 IU 100 000 IU 30 mg	Solution for injection	Cattle, dogs, goats, horses, pigs, rabbits, sheep	For intramuscular use
Slovak Republic	Pharmagal Ltd. Murgašova 5, 949 01 Nitra Slovak Republic	Triavit injekčný roztok	Retinoli palmitas Colecalciferolum Tocoferoli alfa acetas	1 ml: 100 000 IU 50 000 IU 50 mg	Solution for injection	Cattle, horses, calves, pigs, foals, lambs, piglets, dogs, rabbits, poultry	For intramuscular and subcutaneous use
Slovak Republic	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Vitasol AD3EC injekčný roztok	Retinoli palmitas Colecalciferolum Tocoferoli alfa acetas Acidum ascorbicum	1 ml: 50 000 IU 25 000 IU 30 mg 100 mg	Solution for injection	Horses, cattle, pigs, dogs	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Slovenia	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Belavit AD3E, raztopina za injiciranje za konje, govedo, prašiče in pse	Retinol palmitate (vitamin A) Vitamin D3 Vitamin E acetate	176,47 mg (300 000 IU) 100 mg per ml 50 mg per ml	Solution for injection	Cattle, pigs, horses, dogs	For intramuscular and subcutaneous use
Slovenia	Krka, d.d., Novo mesto Šmarješka cesta 6 8501 Novo mesto Slovenia	Vitamin AD3E Krka emulzija za injiciranje za govedo, konje, prašiče, ovce, koze, kunce, pse in mačke	Vitamin A Cholecalciferol Tocopheryl acetate (vitamin E)	50 000 IU/ml 25 000 IU/ml 20 mg/ml	Emulsion for injection	Cattle, horses, pigs, sheep, goats, dogs, cats, rabbits	For intramuscular and subcutaneous use
Spain	S.P Veterinaria, S.A. Ctra. Reus-Vinyols, km 4.1, Riudoms (Tarragona) Spain	ADEX-3-emulsion inyectable	Vitamin A (retinyl palmitate) Cholecalciferol (vitamin D3) All-rac-α-tocopheryl acetate (vitamin E)	50 000 IU 25 000 IU 20 mg	Emulsion for injection	Cattle, goats, horses (foals), pigs, sheep	For intramuscular use
Spain	S.P Veterinaria, S.A. Ctra. Reus-Vinyols, km 4.1, Riudoms (Tarragona) Spain	ADEX-3-Forte	Vitamin A (retinyl propionate) Cholecalciferol (vitamin D3) All-rac-α-tocopheryl acetate (vitamin E)	500 000 IU 75 000 UI 50 mg	Solution for injection	Cattle, goats, pigs, sheep	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Belavit AD3	Vitamin A (retinyl palmitate) Cholecalciferol (vitamin D3) All-rac-α-tocopheryl acetate (vitamin E)	176,47 mg 100 mg 50 mg	Solution for injection	Cattle, pigs, horses, dogs	For intramuscular and subcutaneous use
Spain	Laboratorios Ovejero, S.A., Ctra. Leon-Vilecha No. 30, 24192 Leon, Spain	Biosvita AD3E parenteral emulsion inyectable	Vitamin A (retinyl palmitate) All-rac-α-tocopheryl acetate (vitamin E) Cholecalciferol (vitamin D3)	75 000 IU 15 000 UI 30 mg	Emulsion for injection	Cattle, sheep, goats, pigs, horses	For intramuscular use
Spain	Laboratorios Hipra, S.A. Avda. La Selva, 135 Amer - Gerona 17170 Spain	Hipravit-AD3E Forte	Vitamin A (retinyl palmitate) Cholecalciferol (vitamin D3) All-rac-α-tocopheryl acetate (vitamin E)	500 000 IU 75 000 UI 50 mg	Solution for injection	Cattle, pigs, sheep, horses, rabbits	For intramuscular use
Spain	Labiana Life Sciences S.A. Venus, 26 Terrassa 08228 Barcelona Spain	Labhidro AD3E Solucion inyectable	Vitamin A (retinyl palmitate) Cholecalciferol (vitamin D3) All-rac-α-tocopheryl acetate (vitamin E)	500 000 IU 75 000 UI 50 mg	Solution for injection	Cattle, horses, pigs, sheep	For intramuscular use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Labiana Life Sciences S.A. Venus, 26 Terrassa 08228 Barcelona Spain	NOV-A-VIT emulsion inyectable	Vitamin A (retinyl propionate) Cholecalciferol (vitamin D3) All-rac-α-tocopheryl acetate (vitamin E)	500 000 IU 75 000 IU 50 mg	Emulsion for injection	Cattle, goats, pigs, sheep	For intramuscular use
Spain	Divasa-Farmavic, S.A. Ctra. Sant Hipòlit, km 71 08503 GURB - VIC Barcelona Spain	Polivit AD3E solucion inyectable	Vitamin A (retinyl palmitate) Cholecalciferol (vitamin D3) All-rac-α-tocopheryl acetate (vitamin E)	500 000 IU 75 000 IU 50 IU	Solution for injection	Cattle, sheep, pigs	For intramuscular use
Spain	Laboratorios Ovejero, S.A., Ctra. Leon-Vilecha 30, 24192 Leon, Spain	Polyfil	Phosphorylcholine, retinol, vitamin B12, vitamin E	80 g 5 000 IU 0,05 mg 20 g	Emulsion for injection	Cattle, horses, pigs	For intramuscular use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Fatro Iberica, S.L. Constitucion, 1 - Planta baja, 3 Sant Just Desvern (Barcelona) 08960 Spain	Vetidina AD3E	Vitamin A (retinyl palmitate) Cholecalciferol (vitamin D3) All-rac-α-tocopheryl acetate (vitamin E)	500 000 IU 75 000 UI 50 mg	Solution for injection	Cattle, pigs, sheep	For intramuscular use
Spain	Cenavisa, S.L. Cami Pedra Estela s/n Reus (Tarragona) 43205 Spain	Vitacen AD3E	Vitamin A (retinyl palmitate) Cholecalciferol (vitamin D3) All-rac-α-tocopheryl acetate (vitamin E)	500 000 IU 75 000 UI 50 mg	Solution for injection	Cattle, sheep, goats, pigs, horses	For intramuscular use
Spain	Chemical Iberica Productos Veterinarios, S.L., CR. Burgos-Portugal, Km. 256, Calzada de Don Diego (Salamanca), 37448, Spain	Vitachemical ADE Masivo	Vitamin A (retinyl palmitate) Cholecalciferol (vitamin D3) All-rac-α-tocopheryl acetate (vitamin E)	30 000 UI 10 000 UI 12,5 mg	Solution for injection	Cattle, pigs, sheep, goats, horses	For intramuscular use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Industrial Veterinaria, s.a. C/ Esmeralda 19 Esplugues de Llobregat 08950 Barcelona Spain	Vitamina AD3E Solucion inyectable	Vitamin A (retinyl palmitate) Cholecalciferol (vitamin D3) All-rac-α-tocopheryl acetate (vitamin E)	500 000 IU 75 000 IU 50 mg	Solution for injection	Cattle, sheep, goats, pigs	For intramuscular use
Spain	Super's Diana, S.L. Ctra. C-17, km 17 08150 Parets del Vallès Barcelona Spain	Vitaminas ADE Super's Diana solución inyectable	Vitamin A (retinyl palmitate) Cholecalciferol (vitamin D3) All-rac-α-tocopheryl acetate (vitamin E)	100 000 IU 50 000 IU 50 mg	Solution for injection	Cattle, pigs, sheep, horses, poultry (broilers, duck broilers, turkeys for meat production), dogs	For intramuscular use
Spain	Laboratorios e Industrias Iven, S.A. Luís I, 56 28031 Madrid Spain	Vitamiven A-D-E Solución inyectable	Vitamin A (retinyl palmitate) Cholecalciferol (vitamin D3) All-rac-α-tocopheryl acetate (vitamin E)	300 000 IU 100 000 IU 50 mg	Solution for injection	Cattle, sheep, goats, horses, pigs	For intramuscular use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
Spain	Laboratorios e Industrias Iven, S.A. Luís I, 56 28031 Madrid Spain	Vitamiven complejo solucion inyectable	Vitamin A (retinyl palmitate) Cholecalciferol (vitamin D3) All-rac-α-tocopheryl acetate (vitamin E) thiamine hydrochloride (vitamin B1) Riboflavin sodium phosphate (vitamin B2) Nicotinamide (vitamin B3) Dexpanthenol (vitamin B5) Pyridoxine hydrochloride (vitamin B6) Cyanocobalamin (vitamin B12)	30 000 IU 10 000 IU 5 mg 25 mg 4 mg 50 mg 25 mg 20 mg 0,05 mg	Solution for injection	Cattle, sheep, goats, horses, pigs, dogs, cats	For intramuscular use
Sweden	Pharmaxim AB Stenbrovägen 32 253 68 Helsingborg Sweden	Ultrasan vet	RRR-alpha-tocopheryl acetate, ergocalciferol, retinol palmitate	1 ml: 100 mg, 50 000 IU, 100 000 IU	Solution for injection	Horses, cattle, sheep, dogs, pigs	For intramuscular use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
The Netherlands	Kombivet B.V. Raadhuisstraat 124 Hoogerheide The Netherlands	Adedri-Kel (100 + 50 + 5)	Vitamine A Cholecalciferol Alfa-tocopherolacetate	100 000 IU 50 000 IU 5 mg	Solution for injection	Cattle, horses, pigs, sheep, goats	For intramuscular use
The Netherlands	Aesculaap Groothandel B.V. Mijlstraat 35 Boxtel 5281 LJ The Netherlands	Aescavit	Cholecalciferol Cyanocobalamin sodiumpantothenate Nicotinamid Retinolacetate Riboflavin Sodiumphosphate Anhydrate Thiaminehydrochlorid Tocoferol, DL-alfa acetate	25 000 IU/ml 20 µg/ml 2,8 mg/ml 10 mg/ml 25 000 IU/ml 0,7 mg/ml 10 mg/ml 5 mg/ml	Solution for injection	Horses, foals, cattle, pigs, piglets, sheep, lambs, cats, minks	For intramuscular and subcutaneous use
The Netherlands	Alfasan Nederland B.V. Kuipersweg 9 Woerden 3449 JA The Netherlands	Multivitamin Pro inj.	Vitamin A Cholecalciferole Alfa-tocoferolacetate Thiaminhydrochlorid Riboflavin sodiumphosphate Pyridoxin hydrochlorid Cyanocobalamin Nicotinamid D-panthenole	15 000IU 1 000 IU 20 mg 10 mg 6,85 mg 3 mg 50 µg 35 mg 25 mg	Solution for injection	Cattle, lambs, pigs, piglets	For intramuscular use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
The Netherlands	Alfasan Nederland B.V. Kuipersweg 9 Woerden 3449 JA The Netherlands	Vitamine AD3 80/40 Pro inj.	Vitamin A Cholecaliferole Alfa-tocoferolacetate	80 000 IU 40 000 IU 10 mg	Solution for injection	Cattle, calves, horses, foals, sheep, goats, pigs, piglets, dogs, cats	For intramuscular and subcutaneous use
The Netherlands	Alfasan Nederland B.V. Kuipersweg 9 Woerden 3449 JA The Netherlands	Vitamine AD3 80/40, oplossing voor injectie	Vitamin A Cholecaliferole Alfa-tocooferolacetate	80 000 IU 40 000 IU 10 mg	Solution for injection	Cattle, calves, horses, foals, sheep, goats, pigs, piglets	For intramuscular and subcutaneous use
The Netherlands	Alfasan Nederland B.V. Kuipersweg 9 Woerden 3449 JA The Netherlands	Vitamine AD3E 450.000 Pro inj.	Vitamin A Cholecaliferole Alfa-tocooferolacetate	300 000 IU 100 000 IU 50 mg	Solution for injection	Cattle, calves, horses, foals, pigs, piglets, sheep, goats	For intramuscular and subcutaneous use

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
United Kingdom (Northern Ireland)[1]	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Belavit AD3E, Solution for Injection for horses, cattle, pigs, and dogs	Retinol palmitate All-rac alpha tocopheryl acetate Oily solution of cholecalciferol	176,47 mg 50 mg 100 mg	Solution for injection	Cattle, pigs, horses, dogs	For intramuscular and subcutaneous use

[1] For the United Kingdom, as from 1 January 2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI.

Annex IB

List of authorised veterinary medicinal products recommended for suspension of the marketing authorisation

Member State EU/EEA	Marketing authorisation holders	Name	INN	Strength	Pharmaceutical form	Animal species	Route of administration
France	Ceva Santé Animale 10 Av. de le Ballestiere 33500 Libourne France	Multivit 500	Retinol (as propionate), Cholecalciferol, Alpha-tocopherol (as acetate)	500 000 IU per ml 75 000 IU per ml 50 mg per ml	Solution for injection	Cattle, sheep, pigs	For subcutaneous use

Annex II

Scientific conclusions and grounds for amendment of the summary of product characteristics, labelling and package leaflet for products as referred to in Annex IA and for suspension of the marketing authorisation for the product listed in Annex IB

Overall summary of the scientific evaluation of injectable veterinary medicinal products containing vitamin A for use in food producing species (see Annexes IA and IB)

1. Introduction

Injectable veterinary medicinal products containing vitamin A (retinol and its esters) as sole active substance or in combination with other active substances are used, for example, for the treatment and prevention of vitamin A deficiencies, decreased fertility, growth-related abnormalities such as rickets, maintenance therapy for stressful situations, diarrhoea and infectious diseases, during pregnancy and lactation as well as for stimulation of growth and productivity.

Vitamin A is listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010, with a 'no maximum residue limit (MRL) required' classification for all food producing species. However, the MRL Summary Report (EMEA/MRL/365/98)[2] pointed out that *'Considering the potential of vitamin A for accumulation in liver and injection site, a withdrawal period of appropriate length should be set'.*

Germany noted that a number of injectable veterinary medicinal products containing vitamin A for use in food producing species authorised in various Member States have similar dosage regimens, but different withdrawal periods have been established. For example, the withdrawal periods range from 0 to 60 days for meat and offal and from 0 to 5 days for milk. There were also significant inconsistencies in user safety warnings, ranging from none applied to very detailed user warnings.

In view of the specific toxicological potential of the active substance, the wide differences in the aforementioned withdrawal periods and the inconsistencies in user safety warnings approved for similar products on the market, Germany considered that a re-assessment of the consumer safety as well as of the user safety profile of the injectable veterinary medicinal products containing vitamin A for use in food producing species was needed.

Therefore, Germany considered that it is necessary to refer the matter to the CVMP in the interests of protecting consumer and user safety in the Union.

2. Discussion of data available

Qualitative and quantitative composition

The composition of the 113 veterinary medicinal products concerned by this referral procedure was provided by the marketing authorisation holders or National Competent Authorities. The Committee was to consider the qualitative and quantitative composition of the concerned products, with a view to possible extrapolation of withdrawal periods from one veterinary medicinal product to another.

Both the composition of the products as well as their intended dosages differ between products within a wide range. There are oily and water-based formulations and they include various active substances and excipients as well as a wide range of concentrations of vitamin A.

Overall, based on the different products' composition as well as the shortcomings in residue depletion data and pharmacokinetic data, it was not possible to derive withdrawal periods for groups of similar products based on their composition (formulation and concentration of vitamin A).

[2] EMEA, 1998. Committee for Veterinary Medicinal Products: Summary Report on Vitamin A (EMEA/MRL/365/98) – link

Residue depletion data

Only residue depletion studies from public literature were available which were not conducted according to current guidelines (e.g. VICH GL 48[3]) and current good laboratory practice (GLP) requirements. These studies contain several shortcomings concerning the number of animals per group, tissue sampling, the description of analytical methods and the level of detail of the reported data.

Most studies dealt with concentrations of vitamin A in liver, few studies provided data obtained from injection sites and other edible tissues. Data were available only for the major target species (cattle, pigs, sheep, chickens).

Furthermore, in most of the studies samples were only taken at one timepoint and/or at very early timepoints, thus not allowing the evaluation of residue depletion.

Study reports contained no individual animal data and most of the measured concentrations were reported as means per group. In some of the very old studies, it is not clear what the reported values represent (e.g. arithmetic or geometric mean). In many cases, no measure of variability is reported, i.e. the spread of values is unknown. The only exemption is the study conducted by Kring *et al.* (1958)[4], in which individual animal data is reported, albeit only 1 to 3 animals per timepoint were used.

Moreover, only residue studies after single intramuscular administration were available and animals that were well supplied with vitamin A via feed had already high vitamin A concentrations in edible tissues.

For all of the above-mentioned reasons, the usual approach to derive withdrawal periods based on residue depletion studies for the various target species at the intended doses and for each veterinary medicinal product concerned could not be applied.

The CVMP acknowledged the importance of the veterinary medicinal products for the treatment of vitamin A deficiency and therefore, in the interest of animal welfare and availability of veterinary medicines, the Committee agreed, in this particular case, to consider a pragmatic approach for the calculation of withdrawal periods for the products concerned only. It should be noted that the method used to calculate the withdrawal periods in this specific case does not represent endorsement of the approach as a generic method for establishing withdrawal periods.

The overall vitamin A exposure from residues of veterinary medicinal products in animal derived food (including injection site) plus intake via other food needs to be below 10,000 IU in adults[2]. According to EFSA, intake via other food varies in a range of 2,700 up to 5,000 IU of vitamin A per person per day, leaving a range of 5,000 to 7,300 IU of vitamin A for residues from veterinary medicinal products. 2,500 IU of vitamin A was considered an appropriate limit for residues from injection sites, leaving space for residues in liver, milk and other tissues.

Withdrawal periods for edible tissues were calculated per product based on the maximum dose of vitamin A administered per target species and using an estimated half-life of vitamin A in injection sites. It was calculated at which time after treatment the initial dose at the injection sites would deplete to concentrations below the relevant upper tolerable intake value (2,500 IU of vitamin A).

Only few data on the half-life of vitamin A at injection sites are available from the public literature. According to Kring *et al* (1958)[4], 7 days after treatment with an oily formulation, 84% of the dose (i.e.

[3] VICH topic GL48: Studies to evaluate the metabolism and residue kinetics of veterinary drugs in food-producing animals: marker residue depletion studies to establish product withdrawal periods (EMA/CVMP/VICH/463199/2009) – link
[4] Kring, P. L.; Lund, A. (1958). Absorption and Utilization of Vitamin A Given by Different Routes. Acta Pharmacologica et Toxicologica, Volume 15, p 189-196

420,000 IU) was still present at the injection site in pigs. This would result in a half-life of 28 days. In another study cited in the MRL Summary Report (EMEA/MRL/365/98)[2], after intramuscular administration of 500,000 IU of vitamin A per pig in an oily formulation, 228,000 IU and 87,000 IU of vitamin A remained at the injection site after 25 and 32 days, respectively. This would result in half-life of 15 days (day 0 to day 32), respectively.

In both studies the number of timepoints is insufficient – in one study only one animal was used and in the other study the number of animals is unknown and only mean values were reported – and hence the resulting half-lives are associated with a high uncertainty. To take this and also some further shortcomings into account (i.e. data from two formulations only which were not part of the referral procedure [the composition of one product is unknown, the formulation used in the second study is not authorised as a veterinary medicinal product], data for one species only [pigs] and unknown kinetics at injection site [most likely not linear]), it was concluded that the longest available half-life of 28 days was used for estimation of withdrawal periods. None of the studies allowed derivation of half-lives for residues at injection sites after use of aqueous formulations. As aqueous formulations are likely to deplete faster from injection sites, the estimation based on a half-life of 28 days would also ensure that residues of these formulations are sufficiently low in this tissue.

It was acknowledged that there are some uncertainties in the data with respect to the terminal half-life and dose linearity of the depletion kinetics, both being important parameters for making more reliable estimations. However, in the context of this referral procedure, where products are already authorised and where limited residue depletion data are available, use of this pragmatic approach was considered to be an acceptable way to maintain the availability of medicinal products while ensuring consumer safety.

It is considered that the withdrawal periods proposed for injection site tissues are sufficiently long to cover residue depletion also occurring in the liver of animals treated with the veterinary medicinal products concerned. This can only be justified if withdrawal periods are calculated based on the total dose of vitamin A per animal, as mentioned above. Hence, dividing the dose over several injection sites and using parts of the total dose as the basis for withdrawal period calculation was not considered possible in this particular case.

It was noted that within the scope of this referral there are identical or similar veterinary medicinal products from several MAHs which are authorised in various Member States with different dosage regimens. This referral focused on the review of residue depletion data and recommendation of appropriate withdrawal periods, and the revision or harmonisation of dosage regimens were not within the scope of this procedure. Therefore, since withdrawal periods for meat and offal are based on the maximum intended doses of vitamin A per target species, this would lead to different withdrawal periods for identical or similar products as authorised in the different Member States.

For the products intended for use in animals producing milk for human consumption, there was only one study (Flachowsky *et al.,* 1985)[5] available reporting residue concentrations in milk. This study was conducted in dairy cows around partum and concentrations of vitamin A were measured in colostrum only. Although the situation directly after onset of milk production differs from the one in animals during the subsequent lactation period, the CVMP considered that these data can be taken as a worst-case scenario to make an estimation for withdrawal periods in milk. Vitamin A concentration in first milking would lead to consumer intake of 1.5-fold the tolerable upper intake of 10,000 IU. Residues depleted to concentrations of approximately 2,500 IU after 9–10 milkings.

[5] Flachowsky *et al.* (1985). Der Einfluß unterschiedlicher Vitamin-A-Applikationsformen auf den Vitamin-A-Status von Milchkuh und Kalb. Mh. Vet.-Med. 40, p. 73-76

No residue data in eggs were available. Although a concern regarding consumer safety has been identified, no residue data in poultry have been presented in order to address the concern.

Based on the available data, the CVMP considered that additional risk mitigation measures should be proposed to further ensure consumer safety.

Use of the products needs to be restricted to animals suffering from vitamin A deficiency, because available data clearly indicate that concentrations in edible tissues and milk were much higher in animals with sufficient vitamin A supply compared to vitamin A deficient animals. Therefore, all prevention or prophylaxis indications need to be removed from the product information to further ensure consumer safety. The concerned veterinary medicinal products should be contraindicated in food producing animals with adequate vitamin A supply due to the possibility of accumulation in edible tissues.

Since vitamin A has the potential to accumulate, there is insufficient information on vitamin A concentrations after repeated treatments, and the withdrawal periods are based on data obtained after a single administration, any recommendations for repeated treatment and to the possibility of increasing the dose beyond the stated maximum doses in food producing species need to be removed from the product information.

According to Hidiroglou *et al.* (1996)[6], absorption after subcutaneous use is likely to differ from absorption after intramuscular use and/or intravenous use. Therefore, the concerned veterinary medicinal products should not be used by the subcutaneous route of administration in food producing species.

During the assessment it was noted that the veterinary medicinal product Multivit 500 (as authorised in France by the marketing authorisation holder Ceva Santé Animale), is authorised to be administered by the subcutaneous route only and no residue depletion data to justify a withdrawal period were provided.

Furthermore, for the veterinary medicinal product Izotrevit, soluzione iniettabile per bovini, ovini e suini (as authorised in Italy by the marketing authorisation holder Izo s.r.l. a socio unico), it was noted that, for the target species sheep, only the subcutaneous route of administration is authorised and no residue depletion data for sheep to justify a withdrawal period were provided.

User safety

Symptoms of hypervitaminosis may occur at high doses of 2 to 5 million IU of vitamin A in humans (effect level), or 1.4 to 3.5 million IU of vitamin A when adjusted for systemic availability following injection. A no-effect level with regard to a single exposure is not available, and the vitamin A concentrations in the concerned products were generally high. Therefore, a warning phrase on hypervitaminosis was considered necessary in the product information of the concerned products.

With regard to teratogenicity, exposure from accidental self-injection may result in exposure levels up to 50 times above the tolerable upper intake level. For a few products, exposure was arithmetically at or below the tolerable upper intake level. However, due to the high vitamin A concentrations in the products, a slightly higher injection volume (e.g. 0.3 ml instead of 0.2 ml) might quickly result in an exposure above the tolerable upper intake level. A warning phrase to protect pregnant women who administer the product was considered necessary for the concerned products.

[6] M. Hidiroglou, *et al.* (1996). Distribution of radiovitamin A administered to sheep by four routes. Journal of animal physiology and animal nutrition 75: 142-155

3. Benefit-risk assessment

Introduction

The CVMP was requested to review all available residue depletion data and recommend appropriate withdrawal periods for milk, meat and offal derived from treated animals. The CVMP was further requested to consider whether other risk management measures to deal with residues are feasible for the products under consideration, and assess possible user exposure due to accidental self-injection and the resulting risk, with a view to recommending appropriate user safety warnings in line with the current guidelines.

Benefit assessment

While the efficacy of the concerned products in the target species has not been specifically assessed as part of this referral, the veterinary medicinal products under assessment are considered to be effective in the respective target animals.

Risk assessment

Quality, target animal safety and the environmental risk of the concerned veterinary medicinal products have not been assessed in this referral procedure. Furthermore, for generic products bioequivalence was not evaluated, as this has been done within the respective marketing authorisation procedures when the generic products were authorised.

A risk has been identified regarding the lengths of the withdrawal periods for milk, meat and offal as authorised in different Member States, which may be insufficient to allow residues to fall below levels sufficiently low to ensure consumer safety, thereby posing a risk to consumers after oral intake of foodstuffs from animals treated with these products.

Only residue depletion studies from public literature were available, which were not conducted according to current guidelines (e.g. VICH GL 48[3]) and current good laboratory practice (GLP) requirements. These studies contained a number of shortcomings and were not considered suitable for the evaluation of residue depletion.

As a result, the usual approach to derive withdrawal periods based on residue depletion studies for the various target species at the intended doses and for each veterinary medicinal product concerned could not be applied.

The CVMP acknowledged the importance of the veterinary medicinal products for the treatment of vitamin A deficiency and therefore, in the interest of animal welfare and availability of veterinary medicines, the Committee agreed, in this particular case, to consider a pragmatic approach for the calculation of withdrawal periods for the products concerned only. It should be noted that the method used to calculate the withdrawal periods in this specific case does not represent endorsement of the approach as a generic method for establishing withdrawal periods.

Additionally, the user safety warnings included in the product information with regard to accidental self-injection were considered insufficient for the majority of the concerned products based on a risk of hypervitaminosis as well as a risk for the unborn child due to teratogenicity of vitamin A following accidental self-injection of pregnant women administering the product.

Risk management or mitigation measures

Vitamin A is very important for many body functions (including the immune system). Therefore, there is a certain importance to have products on the market allowing to treat deficient animals. However, as animals are normally well-supplied via feed, and residue concentrations in food derived from these

animals would result in consumer exposure levels that are near or even above the upper tolerable intake value, risk mitigation measures are necessary to ensure consumer safety.

Vitamin A was previously evaluated by the CVMP in order to establish maximum residue limits (MRLs) and it is listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010, with a 'no maximum residue limit (MRL) required' classification for all food producing species. The MRL summary report (EMEA/MRL/365/98)[2] pointed out that '*Considering the potential of vitamin A for accumulation in liver and injection site, a withdrawal period of appropriate length should be set*'.

Taking into account the data available, a pragmatic approach to establish withdrawal periods was followed, based on the highest authorised dose of vitamin A in each individual product, a half-life of 28 days and an upper tolerable intake value of 2,500 IU vitamin A.

Withdrawal periods were calculated for all veterinary medicinal products listed in Annex IA, based on the total dose of vitamin A administered to the animal and are rough estimates accounting for several uncertainties (e.g. various target species and differing formulations of the various veterinary medicinal products concerned). Therefore, dividing the dose over several injection sites and using parts of the total dose as the basis for withdrawal period calculation was not considered possible in this particular case.

The proposed withdrawal periods for meat and offal for veterinary medicinal products (as referred to in Annex IA) are listed in Annex IIIB and are considerably longer than the authorised withdrawal periods and therefore provide a significant improvement over the current situation.

The recommended withdrawal periods would be applicable only if none of the other active substances needs longer withdrawal periods.

It was noted that within the scope of this referral there are identical or similar veterinary medicinal products from several MAHs which are authorised in various Member States with different dosage regimens. This referral focused on the review of residue depletion data and recommendation of appropriate withdrawal periods, and the revision or harmonisation of dosage regimens were not within the scope of this procedure. Therefore, since withdrawal periods for meat and offal are based on the maximum intended doses of vitamin A per target species, this would lead to different withdrawal periods for identical or similar products as authorised in the different Member States.

For milk, a withdrawal period of 5 days (120 hours) was established based on data from one study[5] which was conducted in dairy cows and was considered to represent a worst-case scenario. The CVMP concluded that this withdrawal period would also cover sheep and goat milk in this specific referral procedure.

No residue data in eggs were available and, therefore, the CVMP recommended that the veterinary medicinal products concerned should not be used in birds producing or intended to produce eggs for human consumption.

Based on the available data, further risk mitigation measures were recommended. The Committee considered that use of the products in food producing animals with adequate vitamin A supply should be contraindicated due to the possibility of accumulation in edible tissues and all prevention or prophylaxis indications need to be removed from the product information to further ensure consumer safety.

The recommended withdrawal periods are applicable for a single treatment only. Vitamin A has the potential to accumulate and there is insufficient information on vitamin A concentrations after repeated treatments. Consequently, the Committee considered that any recommendations for repeated treatment and to the possibility of increasing the dose beyond the stated maximum doses in food producing species need to be removed from the product information.

In the studies used for estimation of half-lives on which the calculation of the withdrawal periods was based, animals were treated via intramuscular injection. In addition, available data (Hidiroglou *et al.* (1996)[6]) indicate that absorption after subcutaneous use is likely to differ from absorption after intramuscular and/or intravenous administration. Therefore, the Committee considered that the concerned veterinary medicinal products should not be used by subcutaneous route of administration in food producing species.

As a result of the above conclusion, the CVMP considered that the marketing authorisation for the veterinary medicinal product Multivit 500 (as authorised in France by the marketing authorisation holder Ceva Santé Animale) should be suspended because it is authorised to be administered via subcutaneous route only.

Furthermore, for the veterinary medicinal product Izotrevit, soluzione iniettabile per bovini, ovini e suini (as authorised in Italy by the marketing authorisation holder Izo s.r.l. a socio unico), the CVMP recommended the removal of the target species sheep from the marketing authorisation for this product because, for the target species sheep, the product is authorised to be administered via subcutaneous route only.

With regard to the risk to the user in the scenario of accidental self-injection, the Committee considered that the following warnings should be added to the product information (SPC section 4.5 "*Special precautions to be taken by the person administering the veterinary medicinal product to animals*" and corresponding section in the package leaflet):

- In case of accidental self-injection, a risk of hypervitaminosis in relation to vitamin A cannot be excluded. Therefore, administration should be performed with great caution. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
- Studies with vitamin A in laboratory animals have shown evidence of teratogenic effects. Therefore, this product should not be administered by pregnant women.

Evaluation and conclusions on the benefit-risk balance

Having considered the grounds for the referral procedure and the available data, the CVMP concluded that for 112 out of 113 products (as listed in Annex IA), the withdrawal periods for food producing species should be modified as recommended. Also, certain restrictions for the use of the veterinary medicinal products are needed to mitigate the risk for consumer as well as warnings for the user to account for the risk of accidental self-injection.

For these 112 concerned veterinary medicinal products, the overall benefit-risk balance remains positive, subject to the recommended changes in the product information.

For the veterinary medicinal product Multivit 500 (as authorised in France by the marketing authorisation holder Ceva Santé Animale), as listed in Annex IB of the CVMP opinion, only the subcutaneous route of administration is authorised and no residue depletion data to justify a safe withdrawal period were provided. Therefore, the Committee considered that the benefit-risk balance for this veterinary medicinal product is not favourable in the absence of residue depletion data. Consequently, the Committee recommended the suspension of the existing marketing authorisation.

Grounds for amendment of the summary of product characteristics, labelling and package leaflet for the products

as referred to in Annex IA and for the suspension of the marketing authorisation for the product as listed in Annex IB

Whereas,

- on the basis of the available data, the CVMP considered that the withdrawal periods for milk, meat and offal derived from treated cattle, pigs, horses, sheep, goats, rabbits and poultry should be amended for all veterinary medicinal products listed in Annex IA, to provide assurance of consumer safety;
- on the basis of the available data, the CVMP considered that a restriction in the indication, limitations in the administration as well as a contraindication in the product information of all veterinary medicinal products as listed in Annex IA are necessary;
- on the basis of the available data, the CVMP considered that appropriate safety warnings have to be included in the product information of all veterinary medicinal products as listed in Annex IA;
- in the absence of data, the CVMP considered that the withdrawal periods for milk, meat and offal derived from treated sheep cannot be established for the product Izotrevit, soluzione iniettabile per bovini, ovini e suini (as authorised in Italy by the marketing authorisation holder Izo s.r.l. a socio unico), as referred to in Annex IA, and recommended the removal of the target species sheep from the marketing authorisation for this product;
- in the absence of data, the CVMP considered that the withdrawal periods for milk, meat and offal derived from treated food producing animals cannot be established for the product Multivit 500 (as authorised in France by the marketing authorisation holder Ceva Santé Animale), as referred to in Annex IB;
- the CVMP concluded that the overall benefit-risk balance for the products as referred to in Annex IA, remains positive subject to amendments in the product information;
- the CVMP concluded that the overall benefit-risk balance for the product as referred to in Annex IB, is negative due to the lack of residue depletion data to justify a withdrawal period and because only the subcutaneous route of administration is authorised for this product and its use could pose a potential risk for consumer safety.

The CVMP has recommended varying the marketing authorisations for injectable veterinary medicinal products containing vitamin A for use in food producing species as referred to in Annex IA, for which the summary of product characteristics, labelling and package leaflet are set out in Annexes IIIA and IIIB.

Also, the CVMP has recommended the suspension of the marketing authorisation for the product Multivit 500 (marketing authorisation holder Ceva Santé Animale), as referred to in Annex IB. The condition for lifting the suspension of the marketing authorisation for the veterinary medicinal product (as listed in Annex IB) is set out in Annex IV.

Annex III

Amendments in the relevant sections of the summary of product characteristics, labelling and package leaflet and recommended withdrawal periods for meat and offal for all veterinary medicinal products listed in Annex IA

Annex IIIA

Amendments in the relevant sections of the summary of product characteristics, labelling and package leaflet

This referral procedure concerns food producing species only. Hence, any text related to non-food producing species remains unchanged, whereas, for food-producing species, the modifications listed below need to be applied to the relevant target species.

For all veterinary medicinal products listed in Annex IA

Summary of product characteristics

4.2 Indications for use, specifying the target species

Delete, where applicable, any prevention or prophylaxis indication.

4.3 Contraindications

Add the following wording at the beginning of this section:

Do not use in food producing animals with adequate vitamin A supply due to the possibility of accumulation in edible tissues. *[…]*

4.5 Special precautions for use

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In case of accidental self-injection, a risk of hypervitaminosis in relation to vitamin A cannot be excluded. Therefore, administration should be performed with great caution. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Studies with vitamin A in laboratory animals have shown evidence of teratogenic effects. Therefore, this veterinary medicinal product should not be administered by pregnant women. *[…]*

4.9 Amounts to be administered and administration route

Delete, where applicable, any reference to subcutaneous route of administration in food producing species and replace it with the following wording:

This veterinary medicinal product should not be used by subcutaneous route of administration in food producing species. *[…]*

Delete, where applicable, any reference to repeat treatment and to the possibility of increasing the dose beyond the stated maximum doses in food producing species and replace it with the following wording:

In food producing species, this veterinary medicinal product should be administered only once and the recommended dose should not be exceeded. *[…]*

4.11 Withdrawal period(s)

Delete any meat and offal withdrawal period and replace it with the recommended withdrawal periods that can be found in Annex IIIB.

The recommended withdrawal periods in annex IIIB apply to all food producing species listed in section 4.9 of the summary of product characteristics for the relevant individual product.

If in section 4.9 of the summary of product characteristics one dosage is listed for a target species (e.g. cattle), the same term should apply in section 4.11 of the summary of product characteristics.

If several dosages are listed in section 4.9 of the summary of product characteristics for certain age groups or production types of a target species (e.g. cattle, calves, cows), only the general term (cattle) should be mentioned in section 4.11 of the summary of product characteristics as only one withdrawal period per species is set.

If only dosages for a certain age group are listed (e.g. calves) in section 4.9 of the summary of product characteristics, the withdrawal period is applicable for this age group only and the same term should apply in section 4.11 of the summary of product characteristics.

Replace, where applicable, the withdrawal periods for milk- or egg-producing species with the following wording:

Milk: 120 hours (5 days)

Not for use in birds producing or intended to produce eggs for human consumption.

Labelling:

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Delete, where applicable, any reference to subcutaneous route of administration in food producing species and replace it with the following wording:

This veterinary medicinal product should not be used by subcutaneous route of administration in food producing species *[…]*

Delete, where applicable, any reference to repeat treatment in food producing species and replace it with the following wording:

In food producing species, this veterinary medicinal product should be administered only once and the recommended dose should not be exceeded *[…]*

8. WITHDRAWAL PERIOD(S)

Delete any meat and offal withdrawal period and replace it with the withdrawal periods that can be found in Annex IIIB.

The recommended withdrawal periods in annex IIIB apply to all food producing species listed in section 4.9 of the summary of product characteristics for the relevant individual product.

If in section 4.9 of the summary of product characteristics one dosage is listed for a target species (e.g. cattle), the same term should apply in section 8 of the label.

If several dosages are listed in section 4.9 of the summary of product characteristics for certain age groups or production types of a target species (e.g. cattle, calves, cows), only the general term (cattle) should be mentioned in section 8 of the label as only one withdrawal period per species is set.

If only dosages for a certain age group are listed (e.g. calves) in section 4.9 of the summary of product characteristics, the withdrawal period is applicable for this age group only and the same term should apply in section 8 of the label.

Replace, where applicable, the withdrawal periods for milk- or egg-producing species with the following wording:

Milk: 120 hours (5 days)

Not for use in birds producing or intended to produce eggs for human consumption.

Package leaflet:

4. INDICATION(S)

Delete, where applicable, any prevention or prophylaxis indication.

5. CONTRAINDICATIONS

Add the following wording at the beginning of this section:

Do not use in food producing animals with adequate vitamin A supply due to the possibility of accumulation in edible tissues. *[…]*

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Delete, where applicable, any reference to subcutaneous route of administration in food producing species and replace it with the following wording:

This veterinary medicinal product should not be used by subcutaneous route of administration in food producing species. *[…]*

Delete, where applicable, any reference to repeat treatment and to the possibility of increasing the dose beyond the stated maximum doses in food producing species and replace it with the following wording:

In food producing species, this veterinary medicinal product should be administered only once and the recommended dose should not be exceeded. *[…]*

10. WITHDRAWAL PERIOD(S)

Delete any meat and offal withdrawal period and replace it with the withdrawal periods that can be found in Annex IIIB.

The recommended withdrawal periods in annex IIIB apply to all food producing species listed in section 4.9 of the summary of product characteristics for the relevant individual product.

If in section 4.9 of the summary of product characteristics one dosage is listed for a target species (e.g. cattle), the same term should apply in section 10 of the package leaflet.

If several dosages are listed in section 4.9 of the summary of product characteristics for certain age groups or production types of a target species (e.g. cattle, calves, cows), only the general term (cattle) should be mentioned in section 10 of the package leaflet as only one withdrawal period per species is set.

If only dosages for a certain age group are listed (e.g. calves) in section 4.9 of the summary of product characteristics, the withdrawal period is applicable for this age group only and the same term should apply in section 10 of the package leaflet.

Replace, where applicable, the withdrawal periods for milk- or egg-producing species with the following wording:

Milk: 120 hours (5 days)

Not for use in birds producing or intended to produce eggs for human consumption.

12. SPECIAL WARNING(S)

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental self-injection, a risk of hypervitaminosis in relation to vitamin A cannot be excluded. Therefore, administration should be performed with great caution. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Studies with vitamin A in laboratory animals have shown evidence of teratogenic effects. Therefore, this veterinary medicinal product should not be administered by pregnant women. *[…]*

For Izotrevit, soluzione iniettabile per bovini, ovini e suini listed in Annex IA (Marketing Authorisation Holder: Izo s.r.l. a socio unico)

In addition to all the other amendments stated above, all references to target species sheep should be deleted from the summary of product characteristics, labelling and package leaflet.

Annex IIIB

Recommended withdrawal periods for meat and offal for all veterinary medicinal products listed in Annex IA

Member State EU/EEA	Marketing authorisation holders	Name	Recommended withdrawal periods for meat and offal
Austria	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E, Injektionslösung für Rind, Pferd, Schwein und Hund	Cattle: 259 days Pigs: 194 days Horses: 250 days
Austria	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Vitasol AD3E - Injektionslösung für Tiere	Cattle: 252 days Pigs: 215 days Horses: 252 days
Austria	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Vitasol AD3EC - Injektionslösung für Tiere	Cattle: 259 days Pigs: 215 days Horses: 259 days
Belgium	Zoetis Belgium s.a. Rue Laid Burniat, 1 B-1348 Louvain-La-Neuve Belgium	Duphafral AD3E	Cattle: 287 days Pigs: 243 days Horses: 287 days Sheep: 243 days
Belgium	V.M.D. n.v. Hoge Mauw 900 B-2370 Arendonk Belgium	Vitamine A+D3+E	Cattle: 166 days Pigs: 194 days
Bulgaria	Asklep-Pharma Ltd Lyulin 7, bl. 711A, shop 3 Sofia Bulgaria	Norovit	Cattle: 210 days Pigs: 166 days Horses: 210 days Sheep: 166 days
Bulgaria	Biovet JSC 39, Petar Racov Str. 4550 Peshtera Bulgaria	Vialiton solution for inj.	Cattle: 243 days Pigs: 206 days Horses: 243 days
Bulgaria	Vetprom AD 26, Otez Paissij Str. 2400 Radomir Bulgaria	Vitamin AD3E solutio pro injectionibus	Cattle: 138 days Pigs: 101 days Horses: 138 days Sheep: 89 days Goats: 89 days
Bulgaria	Provet S. A. 77, Posidonos Avenue 174 55 Alimos, Attiki Greece	Zingul inj.	Cattle: 231 days Pigs: 200 days Horses: 231 days Sheep: 200 days Goats: 200 days

Member State EU/EEA	Marketing authorisation holders	Name	Recommended withdrawal periods for meat and offal
Croatia	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E pro injectione, otopina za injekciju, za konje, goveda, svinje i pse	Cattle: 259 days Pigs: 194 days Horses: 250 days
Croatia	Krka - Farma d.o.o. Radnička cesta 48 10000 Zagreb Croatia	Vitamin AD3E, emulzija za injekciju, goveda, ovce, koze, konji, svinje, kunići, psi, mačke	Cattle: 243 days Pigs: 215 days Horses: 243 days Sheep: 187 days Goats: 187 days Rabbits: 122 days
Cyprus	Fatro S.p.A. Via Emilia 285 40064 Ozzano dell'Emilia Bologna Italy	Adecon injection Ενέσιμο διάλυμα για βοοειδή, άλογα, χοίρους, πρόβατα και αίγες	Cattle: 243 days Pigs: 215 days Horses: 243 days Sheep: 215 days Goats: 215 days
Cyprus	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Belavit AD3E, ενέσιμο διάλυμα για άλογα, βοοειδή, χοίρους και σκύλους	Cattle: 259 days Pigs: 194 days Horses: 250 days
Czech Republic	Kela NV Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Adedri-kel injekční roztok	Cattle: 266 days Pigs: 222 days Horses: 259 days Sheep: 194 days Goats: 194 days
Czech Republic	Bioveta, a. s. Komenského 212 683 23 Ivanovice na Hané Czech Republic	ADE – vit injekční roztok	Cattle: 243 days Pigs: 228 days Horses: 243 days Sheep: 194 days Goats: 194 days Rabbits: 56 days
Czech Republic	Pharmagal Ltd. Murgašova 5, 949 01 Nitra Slovak Republic	Triavit injekční roztok	Cattle: 243 days Pigs: 228 days Horses: 243 days Sheep: 194 days Rabbits: 56 days Poultry: 56 days
Czech Republic	Alfasan International B.V. Kuipersweg 9 Woerden Utrecht The Netherlands	Vitamin AD3E Alfasan injekční roztok	Cattle: 259 days Pigs: 231 days Horses: 222 days Sheep: 194 days Goats: 194 days
Estonia	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E bela-pharm	Cattle: 259 days Pigs: 194 days Horses: 250 days

Member State EU/EEA	Marketing authorisation holders	Name	Recommended withdrawal periods for meat and offal
Estonia	Alfasan International B.V. Kuipersweg 9 Woerden Utrecht The Netherlands	Vitamin AD3E forte	Cattle: 280 days Horses: 280 days Sheep: 259 days Goats: 259 days
Estonia	Interchemie Werken De Adelaar Eesti AS Vanapere tee 14, Püünsi küla Viimsi vald, Harju maakond 74013 Estonia	Vitol-140	Cattle: 234 days Pigs: 206 days Horses: 234 days Sheep: 196 days
France	Virbac 1ere Avenue 2065 M - L.I.D. 06516 Carros Cedex France	Ad-Ject	Cattle: 308 days Pigs: 271 days Sheep: 243 days
France	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Belavit AD3E Solution for injection for horses, cattle, pigs and dogs	Cattle: 259 days Pigs: 194 days Horses: 250 days
France	Dopharma France 23, Rue du Prieuré Saint Herblon 44150 Vair sur Loire France	Cofavit 500	Cattle: 308 days Pigs: 271 days Sheep: 243 days Goats: 243 days Rabbits: 187 days
France	Laboratoires Biové 3 Rue de Lorraine 62510 Arques France	Trivitase	Cattle: 324 days Pigs: 271 days Sheep: 243 days Goats: 243 days
Germany	Serumwerk Bernburg AG Hallesche Landstrasse 105b 06406 Bernburg Germany	Ursovit AD_3EC, wässrig pro inj.	Cattle: 215 days Pigs: 187 days Horses: 215 days Sheep: 166 days Goats: 166 days Rabbits: 73 days
Germany	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E pro injectione	Cattle: 259 days Pigs: 194 days Horses: 250 days

Member State EU/EEA	Marketing authorisation holders	Name	Recommended withdrawal periods for meat and offal
Germany	AniMedica GmbH Im Südfeld 9 48308 Senden-Bösensell Germany	Vitamin ADE aniMedica	Cattle: 259 days Pigs: 222 days Horses: 231 days Sheep: 231 days Goats: 231 days
Greece	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Belavit AD3E, solution for injection for horses, cattle, pigs and dogs	Cattle: 259 days Pigs: 194 days Horses: 250 days
Greece	A.Nikolakopoulos A.E, 115 Galatsiou Avenue, Galatsi 11146 Athens Greece	Bremervit AD3E	Cattle: 259 days Pigs: 259 days Horses: 259 days Sheep: 222 days Goats: 222 days
Greece	ERFAR Anonymous Industrial Company of Pharmacies, Altani & Mikras Asias 2 St., 15351 Pallini Attikis Athens Greece	Adepur	Cattle: 231 days Pigs: 200 days Horses: 231 days Sheep: 200 days Goats: 200 days
Greece	Hellafarm AE 1st km Paiania-Markopoulou Avenue 19002 Paiania Attiki Athens Greece	Labiasol AD3E-500	Cattle: 280 days Pigs: 259 days Horses: 280 days Sheep: 243 days Goats: 243 days
Greece	Intervet Hellas S.A. 63, Agiou Dimitriou str, GR-174 56 Alimos, Athens Greece	Turlin AD3E	Cattle: 231 days Pigs: 200 days Horses: 231 days Sheep: 200 days Goats: 200 days
Greece	Hellafarm AE 1st km Paiania-Markopoulou Avenue 19002 Paiania Attiki Athens Greece	Vitamin AD3E/New Vet	Cattle: 231 days Pigs: 200 days Horses: 231 days Sheep: 200 days Goats: 200 days

Member State EU/EEA	Marketing authorisation holders	Name	Recommended withdrawal periods for meat and offal
Greece	Eurovet Animal Health B.V. Handelsweg 25 5531 AE Bladel The Netherlands	Vitamine AD3E/Eurovet	Cattle: 234 days Pigs: 224 days Horses: 234 days Sheep: 196 days Goats: 196 days
Greece	Anafasis LTD 3 Santorinis St, Pallouriotissa 1048 Nicosia Cyprus	Vitamins AD3E/Anafasis inj. sol [(50,000+25,000)IU + 20 mg)]/ml	Cattle: 231 days Pigs: 200 days Horses: 231 days Sheep: 200 days Goats: 200 days
Greece	Anafasis LTD 3 Santorinis St, Pallouriotissa 1048 Nicosia Cyprus	Vitamins AD3E/Anafasis inj. sol [(300,000+100,000)IU + 50 mg]/ml	Cattle: 259 days Pigs: 259 days Horses: 259 days Sheep: 222 days Goats: 222 days
Greece	Provet S. A. 77 Posidonos Avenue 174 55 Alimos Attiki Greece	Zingul	Cattle: 231 days Pigs: 200 days Horses: 231 days Sheep: 200 days Goats: 200 days
Hungary	Kela NV Sint Lenaartseweg 48 2320 Hoogstraten Belgium	Neovit AD3E injekció A.U.V.	Cattle: 266 days Pigs: 222 days Horses: 259 days Sheep: 194 days Goats: 194 days
Hungary	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Belavit AD3E 176,47/2,5/50 mg/ml oldatos injekció lovak, szarvasmarhák, sertések, kutyák számára A.U.V.	Cattle: 259 days Pigs: 194 days Horses: 250 days
Hungary	Bio-Vet Kft. 4487 Tiszatelek, Kossuth u. 151. Hungary	Ferriade injekció A.U.V.	Cattle: 122 Pigs: 84 days Sheep: 122 days
Hungary	Univet Ltd. Tullyvin, Cootehill, Co. Cavan, Ireland	Multivitamines oldatos injekció A.U.V.	Cattle: 238 days Pigs: 194 days
Hungary	Bremer Pharma GmbH Werkstrasse 42, 34414 Warburg, Germany	Vitamin AD3E injekció A.U.V.	Cattle: 215 days Pigs: 150 days Horses: 215 days

Member State EU/EEA	Marketing authorisation holders	Name	Recommended withdrawal periods for meat and offal
Iceland	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E pro injectione	Cattle: 259 days Pigs: 194 days Horses: 250 days
Ireland	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Belavit AD3E, solution for injection for horses, cattle, pigs and dogs	Cattle: 259 days Pigs: 194 days Horses: 250 days
Ireland	Chem-Pharm, Ballyvaughan, Co. Clare, Ireland	Multivitamin Injection	Cattle: 210 days Pigs: 166 days Sheep: 166 days
Italy	Ceva Salute Animale S.p.A. Viale Colleoni 15 20864 Agrate Brianza (MB) Italy	Fosforilene Plus, soluzione iniettabile per vitelli, equini, suini, agnelli.	Cattle: 215 days Pigs: 215 days Horses: 243 days Sheep: 56 days
Italy	Fatro S.p.A. Via Emilia 285 40064 Ozzano dell'Emilia Bologna Italy	Adecon, soluzione iniettabile per bovini, equini, suini, ovi-caprini.	Cattle: 243 days Pigs: 215 days Horses: 243 days Sheep: 215 days Goats: 215 days
Italy	Ceva Salute Animale S.p.A. Viale Colleoni 15 20864 Agrate Brianza (MB) Italy	Adisole A-D-E, soluzione iniettabile per bovini, suini, ovini, equini.	Cattle: 243 days Pigs: 215 days Horses: 243 days Sheep: 215 days
Italy	Fatro S.p.A. Via Emilia 285 40064 Ozzano dell'Emilia Bologna Italy	Idrade, emulsione iniettabile per bovini, equini, suini, ovini.	Cattle: 287 days Pigs: 259 days Horses: 287 days Sheep: 243 days
Italy	Izo S.r.l. a socio unico Via San Zeno 99/A 25124 Brescia Italy	Izotrevit, soluzione iniettabile per bovini, ovini e suini	Cattle: 287 days Pigs: 259 days
Italy	Labiana Life Sciences S.A. Venus, 26 Terrassa 08228 Barcelona Spain	Labhidro AD3E 100 N	Cattle: 280 days Pigs: 259 days Horses: 280 days Sheep: 243 days Goats: 243 days

Member State EU/EEA	Marketing authorisation holders	Name	Recommended withdrawal periods for meat and offal
Italy	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E pro injectione, soluzione iniettabile per equini, bovini, suini e cani	Cattle: 259 days Pigs: 194 days Horses: 250 days
Latvia	Krka, d.d., Novo mesto Šmarješka cesta 6 8501 Novo mesto Slovenia	Vitamin AD3E Krka injection emulsija injekcijām liellopiem, zirgiem, cūkām, aitām, kazām, trušiem, suņiem un kaķiem	Cattle: 243 days Pigs: 215 days Horses: 243 days Sheep: 187 days Goats: 187 days Rabbits: 122 days
Latvia	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E pro injectione šķīdums injekcijām zirgiem, liellopiem, cūkām un suņiem	Cattle: 259 days Pigs: 194 days Horses: 250 days
Latvia	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Vitasol AD3EC šķīdums injekcijām zirgiem, liellopiem, cūkām un suņiem	Cattle: 259 days Pigs: 215 days Horses: 259 days
Lithuania	UAB Interchemie werken De Adelaar LT Vinčų g. 3-48 46297 Kaunas Lithuania	Introvit, injekcinis tirpalas galvijams, arkliams, ožkoms, avims ir kiaulėms	Cattle: 182 days Pigs: 166 days Horses: 182 days Sheep: 166 days Goats: 166 days
Lithuania	Bioveta, a. s. Komenského 212 683 23 Ivanovice na Hané Czech Republic	Multivit–Mineral, injekcinis tirpalas	Cattle: 266 days Pigs: 215 days Sheep: 166 days Goats: 166 days
Lithuania	Krka, d.d., Novo mesto Šmarješka cesta 6 8501 Novo mesto Slovenia	Vitamin AD3E Krka injekcinė emulsija	Cattle: 243 days Pigs: 215 days Horses: 243 days Sheep: 187 days Goats: 187 days Rabbits: 122 days
Lithuania	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E injekcinis tirpalas	Cattle: 259 days Pigs: 194 days Horses: 250 days
Lithuania	UAB Interchemie werken De Adelaar LT Vinčų g. 3-48 46297 Kaunas Lithuania	Vitol-140 injekcinis tirpalas	Cattle: 234 days Pigs: 224 days Horses: 234 days Sheep: 185 days Goats: 185 days

Member State EU/EEA	Marketing authorisation holders	Name	Recommended withdrawal periods for meat and offal
Lithuania	Dopharma B.V. Zalmweg 24 4941 VX Raamsdonksveer The Netherlands	Vitol-Ject Forte injekcinis tirpalas	Cattle: 315 days Pigs: 271 days Horses: 308 days Sheep: 243 days
Malta	Fatro S.p.A. Via Emilia 285 40064 Ozzano dell'Emilia Bologna Italy	Adecon	Cattle: 243 days Pigs: 215 days Horses: 243 days Sheep: 215 days Goats: 215 days
Malta	Interchemie werken "De Adelaar" B.V. Metaalweg 8, 5404 CG Venray The Netherlands	Introvit	Cattle: 182 days Pigs: 166 days Horses: 182 days Sheep: 166 days Goats: 166 days
Malta	Labiana Life Sciences S.A Carrer de Venus, 26 08228 Terrassa (Barcelona) Spain	Labhidro AD3E Injectable	Cattle: 280 days Pigs: 259 days Horses: 259 days Sheep: 243 days Goats: 243 days
Malta	Labiana Life Sciences S.A Carrer de Venus, 26 08228 Terrassa (Barcelona) Spain	NOV-A-VIT 500	Cattle: 280 days Pigs: 259 days Sheep: 243 days Goats: 243 days
Malta	Kepro B.V. Maagdenburgstraat 17 7421 ZA Deventer The Netherlands	Vita Flash Inj.	Cattle: 243 days Pigs: 215 days Horses: 243 days Sheep: 215 days Goats: 215 days
Malta	Interchemie werken ''De Adelaar'' LT, Vincu g. 3-48, Kaunas, Lithuania	Vitol-140	Cattle: 234 days Pigs: 224 days Horses: 234 days Sheep: 185 days Goats: 185 days
Norway	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Belavit AD3E vet	Cattle: 259 days Pigs: 194 days Horses: 250 days
Poland	Eurovet Animal Health B.V. Handelsweg 25 5531 AE Bladel The Netherlands	Witamina AD3E 80/40/20 pro.inj.	Cattle: 234 days Pigs: 224 days Horses: 234 days Sheep: 196 days Goats: 196 days

Member State EU/EEA	Marketing authorisation holders	Name	Recommended withdrawal periods for meat and offal
Portugal	Zoetis Portugal, Lda Lagoas Park Edifício 10, 2740-271 Porto Salvo Portugal	Duphafral Multi	Cattle: 194 days Pigs: 129 days Horses: 194 days Sheep: 129 days Goats: 129 days
Portugal	Divasa-Farmavic, S.A. Ctra. Sant Hipòlit, km 71 08503 GURB - VIC Barcelona Spain	Polivit AD3E Solução Injectável para bovinos, suínos, ovinos, caprinos, equinos, cães e gatos. Vitamina A, Vitamina D3, Vitamina E	Cattle: 287 days Pigs: 243 days Horses: 287 days Sheep: 215 days Goats: 215 days
Portugal	Vetlima Sociedade Distribuidora de Produtos Agro-Pecuários, S.A. Centro Empresarial da Rainha, Lote 27 2050-501 Vila Nova da Rainha Portugal	Vitalbion solução injetável para bovinos, ovinos e suínos	Cattle: 287 days Pigs: 259 days Sheep: 243 days
Portugal	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E pro injectione, solução injetável para equídeos, bovinos, suínos e cães	Cattle: 259 days Pigs: 194 days Horses: 250 days
Romania	Interchemie werken "De Adelaar" B.V. Metaalweg 8, 5404 CG Venray The Netherlands	Introvit	Cattle: 182 days Pigs: 166 days Horses: 182 days Sheep: 166 days Goats: 166 days
Romania	Dutch Farm International BV, Nieuw Walden 112, 1394 PE Nederhorst den Berg The Netherlands	Multivit inj.	Cattle: 222 days Pigs: 187 days Horses: 222 days Sheep: 166 days
Romania	S.C. Romvac Company S.A. Şos. Centurii, nr. 7 Voluntari Romania	Multivitarom	Cattle: 243 days Pigs: 185 days Horses: 243 days Sheep: 185 days Goats: 185 days
Romania	S. C. Pasteur - Filiala Filipesti S.A str. Principala, nr.Jud Prahova Romania	Multi-vita-vet	Cattle: 182 days Pigs: 166 days Horses: 182 days Sheep: 166 days Goats: 166 days

Member State EU/EEA	Marketing authorisation holders	Name	Recommended withdrawal periods for meat and offal
Romania	Kepro B.V. Maagdenburgstraat 17 7421 ZA Deventer The Netherlands	Vitaflash	Cattle: 243 days Pigs: 215 days Horses: 215 days Sheep: 166 days
Romania	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Vitamin AD3E	Cattle: 259 days Pigs: 194 days Horses: 259 days
Romania	S.C. Romvac Company S.A. Şos. Centurii, nr. 7 Voluntari Romania	Vitamin AD3E	Cattle: 243 days Pigs: 187 days Horses: 243 days Sheep: 215 days Goats: 215 days Poultry: 73 day
Romania	S. C. Pasteur - Filiala Filipesti S.A str. Principala, nr.Jud Prahova Romania	Vitamina AD3E	Cattle: 252 days Pigs: 215 days Horses: 252 days Sheep: 187 days Goats: 187 days Rabbits: 56 days
Romania	Interchemie Werken De Adelaar Eesti AS Vanapere tee 14, Püünsi küla Viimsi vald, Harju maakond 74013 Estonia	Vitol-140	Cattle: 234 days Pigs: 224 days Horses: 234 days Sheep: 185 days Goats: 185 days
Romania	Alapis S.A. 19 300 Aspropyrgos Mailbox 26 Athens Greece	Zingul AD3E	Cattle: 231 days Pigs: 206 days Horses: 231 days Sheep: 200 days Goats: 200 days
Slovak Republic	Bioveta, a. s. Komenského 212 683 23 Ivanovice na Hané Czech Republic	ADE-vit Injekčný roztok	Cattle: 243 days Pigs: 228 days Horses: 243 days Sheep: 194 days Goats: 194 days Rabbits: 56 days
Slovak Republic	Pharmagal Ltd. Murgašova 5, 949 01 Nitra Slovak Republic	Triavit injekčný roztok	Cattle: 243 days Pigs: 228 days Horses: 243 days Sheep: 194 days Rabbits: 56 days Poultry: 56 days

Member State EU/EEA	Marketing authorisation holders	Name	Recommended withdrawal periods for meat and offal
Slovak Republic	Richter Pharma AG Feldgasse 19 4600 Wels Austria	Vitasol AD3EC injekčný roztok	Cattle: 259 days Pigs: 215 days Horses: 259 days
Slovenia	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Belavit AD3E, raztopina za injiciranje za konje, govedo, prašiče in pse	Cattle: 259 days Pigs: 194 days Horses: 250 days
Slovenia	Krka, d.d., Novo mesto Šmarješka cesta 6 8501 Novo mesto Slovenia	Vitamin AD3E Krka emulzija za injiciranje za govedo, konje, prašiče, ovce, koze, kunce, pse in mačke	Cattle: 243 days Pigs: 215 days Horses: 243 days Sheep: 187 days Goats: 187 days Rabbits: 122 days
Spain	S.P Veterinaria, S.A., Ctra. Reus-Vinyols, km 4.1, Riudoms (Tarragona) Spain	ADEX-3-emulsion inyectable	Cattle: 150 days Pigs: 122 days Horses: 150 days Sheep: 122 days Goats: 122 days
Spain	S.P Veterinaria, S.A., Ctra. Reus-Vinyols, km 4.1, Riudoms (Tarragona) Spain	ADEX-3-Forte	Cattle: 287 days Pigs: 243 days Sheep: 215 days Goats: 215 days
Spain	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Belavit AD3	Cattle: 259 days Pigs: 194 days Horses: 250 days
Spain	Laboratorios Ovejero, S.A., Ctra. Leon-Vilecha No. 30, 24192 Leon, Spain	Biosvita AD3E parenteral emulsion inyectable	Cattle: 231 days Pigs: 231 days Horses: 231 days Sheep: 203 days Goats: 203 days
Spain	Laboratorios Hipra, S.A. Avda. La Selva, 135 Amer - Gerona 17170 Spain	Hipravit-AD3E Forte	Cattle: 280 days Pigs: 243 days Horses: 280 days Sheep: 243 days Rabbits: 187 days
Spain	Labiana Life Sciences S.A. Venus, 26 Terrassa 08228 Barcelona Spain	Labhidro AD3E Solucion inyectable	Cattle: 280 days Pigs: 259 days Horses: 280 days Sheep: 243 days

Member State EU/EEA	Marketing authorisation holders	Name	Recommended withdrawal periods for meat and offal
Spain	Labiana Life Sciences S.A. Venus, 26 Terrassa 08228 Barcelona Spain	NOV-A-VIT emulsion inyectable	Cattle: 280 days Pigs: 259 days Sheep: 243 days Goats: 243 days
Spain	Divasa-Farmavic, S.A. Ctra. Sant Hipòlit, km 71 08503 GURB - VIC Barcelona Spain	Polivit AD3E solucion inyectable	Cattle: 299 days Pigs: 280 days Sheep: 243 days
Spain	Laboratorios Ovejero, S.A., Ctra. Leon-Vilecha No. 30, 24192 Leon, Spain	Polyfil	Cattle: 159 days Pigs: 131 days Horses: 159 days
Spain	Fatro Iberica, S.L. Constitucion, 1 - Planta baja, 3 Sant Just Desvern (Barcelona) 08960 Spain	Vetidina AD3E	Cattle: 287 days Pigs: 259 days Sheep: 215 days
Spain	Cenavisa, S.L. Cami Pedra Estela s/n Reus (Tarragona) 43205 Spain	Vitacen AD3E	Cattle: 271 days Pigs: 259 days Horses: 259 days Sheep: 243 days Goats: 243 days
Spain	Chemical Iberica Productos Veterinarios, S.L., CR. Burgos-Portugal, Km. 256, Calzada de Don Diego (Salamanca), 37448, Spain	Vitachemical ADE Masivo	Cattle: 185 days Pigs: 157 days Horses: 185 days Sheep: 157 days Goats: 157 days
Spain	Industrial Veterinaria, s.a. C/ Esmeralda 19 Esplugues de Llobregat 08950 Barcelona Spain	Vitamina AD3E Solucion inyectable	Cattle: 280 days Pigs: 259 days Sheep: 243 days Goats: 243 days
Spain	Super's Diana, S.L. Ctra. C-17, km 17 08150 Parets del Vallès Barcelona Spain	Vitaminas ADE Super's Diana solución inyectable	Cattle: 243 days Pigs: 187 days Horses: 243 days Sheep: 187 days Poultry: 56 days

Member State EU/EEA	Marketing authorisation holders	Name	Recommended withdrawal periods for meat and offal
Spain	Laboratorios e Industrias Iven, S.A. Luís I, 56 28031 Madrid Spain	Vitamiven A-D-E Solución inyectable	Cattle: 259 days Pigs: 259 days Horses: 259 days Sheep: 238 days Goats: 238 days
Spain	Laboratorios e Industrias Iven, S.A. Luís I, 56 28031 Madrid Spain	Vitamiven complejo solucion inyectable	Cattle: 194 days Pigs: 157 days Horses: 194 days Sheep: 157 days Goats: 157 days
Sweden	Pharmaxim AB Stenbrovägen 32 253 68 Helsingborg Sweden	Ultrasan vet	Cattle: 259 days Pigs: 243 days Horses: 243 days Sheep: 194 days
The Netherlands	Kombivet B.V. Raadhuisstraat 124 Hoogerheide The Netherlands	Adedri-Kel (100 + 50 + 5)	Cattle: 222 days Pigs: 166 days Horses: 166 days Sheep: 157 days Goats: 157 days
The Netherlands	Aesculaap Groothandel B.V. Mijlstraat 35 Boxtel 5281 LJ The Netherlands	Aescavit	Cattle: 259 days Pigs: 215 days Horses: 224 days Sheep: 182 days
The Netherlands	Alfasan Nederland B.V. Kuipersweg 9 Woerden 3449 JA The Netherlands	Multivitamin Pro inj.	Cattle: 166 days Pigs: 138 days Sheep: 138 days
The Netherlands	Alfasan Nederland B.V. Kuipersweg 9 Woerden 3449 JA The Netherlands	Vitamine AD3 80/40 Pro inj.	Cattle: 234 days Pigs: 206 days Horses: 229 days Sheep: 178 days Goats: 178 days
The Netherlands	Alfasan Nederland B.V. Kuipersweg 9 Woerden 3449 JA The Netherlands	Vitamine AD3 80/40, oplossing voor injectie	Cattle: 234 days Pigs: 206 days Horses: 229 days Sheep: 178 days Goats: 178 days
The Netherlands	Alfasan Nederland B.V. Kuipersweg 9 Woerden 3449 JA The Netherlands	Vitamine AD3E 450.000 Pro inj.	Cattle: 259 days Pigs: 231 days Horses: 222 days Sheep: 194 days Goats: 194 days

Member State EU/EEA	Marketing authorisation holders	Name	Recommended withdrawal periods for meat and offal
United Kingdom (Northern Ireland)[7]	Bela-pharm GmbH & Co. KG Lohner Str. 19 49377 Vechta Germany	Belavit AD3E, Solution for Injection for horses, cattle, pigs and dogs	Cattle: 259 days Pigs: 194 days Horses: 250 days

[7] For the United Kingdom, as from 1 January 2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI.

Annex IV

Condition for lifting the suspension of the marketing authorisation for Multivit 500 (MAH: Ceva Santé Animale), as listed in Annex IB

For the suspension of the marketing authorisations for Multivit 500 (as authorised in France by the marketing authorisation holder Ceva Santé Animale) to be lifted, the national competent authority shall ensure that the following condition is fulfilled by the concerned marketing authorisation holder:

- Residue depletion studies should be provided regardless of whether the route of administration has changed or not. The withdrawal period should be based on robust and complete data (animal phase and validation of the analytical method) in accordance with the guidelines in force.