



DRUGS DEPARTMENT

TITLE: VETERINARY BIOLOGICAL AND IMMUNOLOGICAL PRODUCTS REGISTER

Doc. N^o: DAR/FOM/172
 Revision N^o: 1
 Effective Date: 21 Feb. 2022
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S/N	REGISTRATION NO.	PRODUCT BRAND NAME	ACTIVE PHARMACEUTICAL INGREDIENTS	DOSAGE STRENGTH	DOSAGE FORM	PACK SIZE	PACKAGING TYPE	SHELF LIFE	MANUFACTURER AND ADDRESS	MANUFACTURER COUNTRY	MARKET AUTHORIZATION HOLDER (MAH)	LOCAL TECHNICAL REPRESENTATIVE (LTR)	REGISTRATION DATE	EXPIRY DATE
1	RAB/IVPR/EACMR/0001	BIORAL H120 NEO	STRAIN OF AVIAN INFECTIOUS BRONCHITIS, STRAIN H120	AT LEAST 3.7 LOG ₁₀ EID ₅₀	EFFERVESCENT TABLET	1*1*10*200 DOSES	FREEZE-DRIED VACCINE PRESENTED IN BOTTLES	21 MONTHS	MERIAL LABORATORY PORTE DES ALPES RUE DE L'AVIATION, 59800 SAINT PRIEST, FRANCE	FRANCE	MERIAL SAS	SURGIPHARM (RWANDA) LTD	Renewal in process	Renewal in process
2	Rwanda FDA-VBP-MA-001	OXYTOCIN-10	OXYTOCIN 10 IU/ML	10 IU/ML	SOLUTION FOR INJECTION	1 BOTTLE OF 50ML	TYPE II GLASS BOTTLES	24 MONTHS	INTERCHEMIE WERKEN "DE ADELAAR" B.V., Metaalweg 8, 5804 CG Venray, The Netherlands and INTERCHEMIE WERKEN DE ADELAAR EESTI AS, Vanapere tee 14, Püünsi küla, Viimsi vald, Harju maakond, 74013, Estonia	THE NETHERLANDS AND ESTONIA	INTERCHEMIE WERKEN "DE ADELAAR" B.V.	AGROTECH LTD	09 TH AUGUST 2024	08 TH AUGUST 2029
3	Rwanda FDA-VBP-MA-002	OXYTOCIN-20	OXYTOCIN 20 IU/ML	20 IU/ML	SOLUTION FOR INJECTION	1 BOTTLE OF 50ML	TYPE II CLEAR GLASS BOTTLES	36 MONTHS	INTERCHEMIE WERKEN "DE ADELAAR" B.V., Metaalweg 8, 5804 CG Venray, The Netherlands and INTERCHEMIE WERKEN DE ADELAAR EESTI AS, Vanapere tee 14, Püünsi küla, Viimsi vald, Harju maakond, 74013, Estonia	THE NETHERLANDS AND ESTONIA	INTERCHEMIE WERKEN "DE ADELAAR" B.V.	AGROTECH LTD	09 TH AUGUST 2024	08 TH AUGUST 2029
4	Rwanda FDA-IVP-MA-001	IMMUNAFT – PLUS	INACTIVATED PURIFIED ANTIGEN OF EACH STRAIN OF FMD VIRUS, SEROTYPES (A, O, SAT 1 & SAT 2), 6PD50 PER 3ML/DOSE	6PD50 PER 3ML/DOSE	SUSPENSION FOR INJECTION	51 ML, 105 ML AND 210 ML VIALS	Polypropylene plastic bottles or Glass vials with a capacity of 51 ml (17 bovine doses), 105 ml (35 bovine doses) and 210 ml (70 bovine doses), closed with rubber stoppers and sealed with aluminium caps	18 MONTHS	BIOPHARMA, Km2 Route de Casablanca B.P 4569 Rabat-Akkari -10050 Rabat, Morocco	MOROCCO	BIOPHARMA	VET LINKS LTD	09 TH AUGUST 2024	08 TH AUGUST 2029
5	RWA/FDA/DD-MA-VM/01-2023/0489-2023/0002	RB-51	BRUCELLA ABORTUS, STRAIN RB-51, LIVE CULTURE: 10- 34 X 109 CFU PER 2 ML DOSE CFU	10- 34 X 109 CFU PER 2 ML DOSE CFU	LYOPHILISATE AND SOLVENT FOR SUSPENSION FOR INJECTION	5-DOSE (10 Ml) AND 25-DOSE (50 Ml)	The freeze-dried vaccine is packed into Type I glass vials, closed with rubber stopper and sealed with an aluminium cap. The Sterile diluent is filled into sterile type 1 glass vials, closed with a sterile rubber stopper, and sealed with an aluminum seal	36 MONTHS	COLORADO SERUM COMPANY, 4950 York Street, Denver, Colorado 80216-0428 USA	USA	INTERVET SOUTH AFRICA (PTY) LTD, SOUTH AFRICA	AGROTECH LTD	27 TH NOVEMBER 2024	26 TH NOVEMBER 2029

6	RWA/FDA/DD-MA-VM/01-2022/1139-2022/0003	CYSTORELINE	GONADORELIN (AS DIACETATE TETRA HYDRATE) 0.05 MG/ML	0.05 MG/ML	SOLUTION FOR INJECTIO	10 ML, 20 ML AND 50 ML VIALS	GLASS VIAL TYPE II	24 MONTHS	CEVA SANTÉ ANIMALE, 10 avenue de la Ballastière, 33500 Libourne, France	FRANCE	CEVA SANTÉ ANIMALE, FRANCE	AGROTECH LTD	27 TH NOVEMBER 2024	26 TH NOVEMBER 2029
7	RWA/FDA/DD-MA-VM/04-2022/5431-2022/0004	PRID DELTA	PROGESTERONE 1.55 G/DEVICE	1.55 G/DEVICE	VAGINAL DELIVERY SYSTEM	1 DEVICE, 10 SACHETS OF 1 DEVICE AND 100 SACHETS OF 1 DEVICE	PET/ALUMINIUM/PE RECTANGULAR SACHETS	36 MONTHS	CEVA SANTÉ ANIMALE, Zone Industrielle Très Le Bois, 22600 Loudeac	FRANCE	CEVA SANTÉ ANIMALE, FRANCE	AGROTECH LTD	27 TH NOVEMBER 2024	26 TH NOVEMBER 2029
8	RWA/FDA/DD-MA-VBP/07-2022/10717/0005	ENZAPROST T	DINOPROST 5.0 MG/ML	5.0 MG/ML	SOLUTION FOR INJECTION	50 ML VIAL	TYPE I COLOURLESS GLASS VIAL	36 MONTHS	CEVA SANTÉ ANIMALE, 10 avenue de la Ballastière, 33500 Libourne, France	FRANCE	CEVA SANTÉ ANIMALE, FRANCE	AGROTECH LTD	11 TH JUNE 2025	10 TH JUNE 2030
9	RWA/FDA/DD-MA-IVP/11-2022/16656/0003	NOBIVAC® RABIES	INACTIVATED, RABIES VIRUS STRAIN PASTEUR RIV ≥ 0,95 AIU EQUIVALENT TO ≥ 2.0 I.U.	≥ 2.0 I.U	LIGHT YELLOW/ORANGE TO SLIGHTLY RED/PURPLE AQUEOUS SUSPENSION WITH A WHITE SEDIMENT	VIALS OF 1 DOSE OR 10 DOSES	VIAL OF HYDROLYTIC TYPE I GLASS (PH.EUR.), CLOSED WITH A HALOGENBUTYL RUBBER STOPPER AND SEALED WITH AN ALUMINIUM CAP	48 MONTHS	INTERVET INTERNATIONAL B.V. 35 Wim de Körver street, Boxmeer, The Netherlands	THE NETHERLANDS	INTERVET SOUTH AFRICA (PTY) LTD	AGROTECH LTD	11 TH JUNE 2025	10 TH JUNE 2030

Prof. Emile BIENVENU
Director General