



RWANDA FDA
 Rwanda Food and Drugs Authority
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RWANDA FDA EMERGENCY USE AUTHORIZATION PRODUCTS _OCTOBER 2024

S/N	REGISTRATIO N NO.	PRODUCT BRAND NAME	PRODUCT COMMON NAME (INN)	DOSAGE STRENGTH	DOSAGE FORM	PRODUCT CATEGORY	PACK SIZE	PACKAGING TYPE	SHELF LIFE	MANUFACTURER	MANUFACTU RER COUNTRY	MARKET AUTHORIZATIO N HOLDER (MAH)	LOCAL TECHNICA L REPRESEN TATIVE/DR	APPROVAL DATE
1	RWANDA FDA-AEU- 0013/2024	JYNNEOS (SMALLPOX AND MONKEYPOX VACCINE, LIVE, NON- REPLICATING)	LIVE MODIFIED VACCINIA ANKARA- BAVARIAN NORDIC (MVV-A-BN) STRAIN, AN ATTENUATED, NON-REPLICATING ORTHOPOXYVIRUS	5 X 107 TCID50 PER 0.5 ML DOSE	SUSPENSION FOR INJECTION FOR SUBCUTANEOU S ADMINISTRATI ON	HUMAN	BOXES OF 10 OR 20 VIALS	SINGLE-DOSE TYPE I GLASS VIALS	24 MONTHS WHEN STORED AT - 20°C ± 5°C PROTECTED FROM LIGHT	BAVARIAN NORDIC A/S PHILIP HEYMANS ALLE 3 2900 HELLERUP DENMARK	DENMARK	BAVARIAN NORDIC A/S PHILIP HEYMANS ALLE 3 DK-2900 HELLERUP, DENMARK	N/A	14/09/2024
2	RWANDA FDA-EUA- 0014/2024	VEKLURY™ (REMEDSIVIR)	VEKLURY™ (REMEDSIVIR)	100 MG/20 ML (5 MG/ML) OF VEKLURY CONCENTRAT ED SOLUTION	LYOPHILIZED POWDER FOR INJECTION	HUMAN	SINGLE-DOSE CLEAR GLASS VIAL	SINGLE-DOSE CLEAR GLASS VIAL	48 MONTHS	GILEAD SCIENCES, INC., CA USA	USA	GILEAD SCIENCES, INC., CA USA	N/A	05/10/2024

(Handwritten signature)

Prof. Emile BIENVENU
 Director General

