



REGISTRATION CERTIFICATE OF HUMAN MEDICINAL PRODUCT

Made under Law No. 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning in its article 3 and article 8 and regulation No. CBD/TRG/010. The Authority here issues

Registration number: Rwanda FDA-HMP-MA-0748

This is to certify that the Human Medicine described below has been registered in Rwanda subject to conditions indicated at the back of this certificate.

Brand Name: Xarelto-20 Tablets.

Name of the Active ingredient(s) and Strength: Rivaroxaban 20mg.

Therapeutic Indication: Xarelto, co-administered with acetylsalicylic acid (ASA) alone or with ASA plus clopidogrel or ticlopidine, is indicated for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers; in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischemic events.

Dosage Form and appearance: Film Coated tablets, round, biconvex, brown red tablets. Bayer-cross on one side and triangle and 20 on the other side.

Pack size and Packaging type: Blister PP/Alu 1x14's tablets.

Shelf life in months and Storage statement: 36 months. Do not store above 30°C.

Distribution category: POM.

Name of Marketing Authorization Holder: Bayer East Africa Limited.

Name and address of Manufacturer: Bayer AG, Kaiser-Wilhelm-Allee 51368 Leverkusen, Germany.

Name of Local Technical Representative: Surgipharm Rwanda Ltd.

Issued on: 15/01/2024

Expires on: 14/01/2029



Dr. Emile BIENVENU
Director General

Conditions for Human Medicinal Product Registration

1. This certificate must be returned to the Authority if canceled, invalidated or if the registered Human Medicinal Product is withdrawn.
2. Any change in the information submitted for the purpose of registration must be notified to the Rwanda FDA within 30 days of the change.
3. This certificate shall be invalid immediately after the expiry date and the Marketing Authorization Holder shall ensure that application for renewal of registration is made 90 days before expiry of registration.
4. Registered Human Medicinal Product cannot be advertised without prior approval of the Authority.
5. The Human Medicinal Product shall comply with all relevant provisions of Rwanda FDA regulations at all times.
6. The Marketing Authorization Holder shall ensure that the Human Medicinal Product complies with Rwandan labelling and packaging requirements at all times.
7. The Marketing Authorization Holder shall ensure that the manufacturing facilities where a registered Human Medicinal Product is produced comply at all times with Rwanda FDA Good Manufacturing Practice requirements.
8. The Marketing Authorization Holder shall notify Rwanda FDA of the change of a Local Technical Representative at all times.
9. The registration of the Human Medicinal Product shall continue to be valid for five (5) years provided that annual retention fee is paid.
10. The Marketing Authorization Holder shall ensure to update the SmPC, PIL and Labeling with registration number and submit the updated document to the Authority before the first shipment.
11. The Authority reserves the right to withdrawal this certificate when conditions 1 to 7 are contravened and when the risks of using this medicine outweighs the benefits or it is in public interest to do so.

