VAXATO 2.5 MG Film Coated Tablets

SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

1. NAME OF THE MEDICINAL PRODUCT

Vaxato 2.5 mg film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains 2.5 mg rivaroxaban.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet

Yellow to dark beige, round, biconvex, unscored film coated tablets engraved with"2.5" on one side and plain on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Vaxato, 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 (see sections 4.3, 4.4 and 5.1).

Vaxato, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with coronary artery disease (CAD) or symptomatic peripheral artery disease (PAD) at high risk of ischaemic events.

4.2 Posology and method of administration

Posology

The recommended dose is 2.5 mg twice daily.

- *ACS*

Patients taking Vaxato 2.5 mg twice daily should also take a daily dose of 75 - 100 mg ASA or a daily dose of 75 - 100 mg ASA in addition to either a daily dose of 75 mg clopidogrel or a standard daily dose of ticlopidine.

Treatment should be regularly evaluated in the individual patient weighing the risk for ischaemic events against the bleeding risks. Extension of treatment beyond 12 months should be done on an individual patient basis as experience up to 24 months is limited (see section 5.1).

Treatment with Vaxato should be started as soon as possible after stabilisation of the ACS event (including revascularisation procedures); at the earliest 24 hours after admission to hospital and at the time when parenteral anticoagulation therapy would normally be discontinued.

- *CAD/PAD*

Patients taking Vaxato 2.5 mg twice daily should also take a daily dose of 75 - 100 mg ASA.

Duration of treatment should be determined for each individual patient based on regular evaluations and should consider the risk for thrombotic events versus the bleeding risks.

In patients with an acute thrombotic event or vascular procedure and a need for dual antiplatelet therapy, the continuation of Vaxato 2.5 mg twice daily should be evaluated depending on the type of event or procedure and antiplatelet regimen. Safety and efficacy of Vaxato 2.5 mg twice daily in combination with ASA plus clopidogrel/ticlopidine has only been studied in patients with recent ACS (see section 4.1). Dual antiplatelet therapy has not been studied in combination with Vaxato 2.5 mg twice daily in patients with CAD/PAD (see sections 4.4 and 5.1).

If a dose is missed the patient should continue with the regular dose as recommended at the next scheduled time. The dose should not be doubled to make up for a missed dose.

General Directorate of Registration Approval Date: 18 / 1/2021 Revised by Rania.M.Kamel
Pharmacology Department According to Germany

Converting from Vitamin K Antagonists (VKA) to Vaxato

When converting patients from VKAs to Vaxato, International Normalised Ratio (INR) values could be falsely elevated after the intake of Vaxato. The INR is not valid to measure the anticoagulant activity of Vaxato, and therefore should not be used (see section 4.5).

Converting from Vaxato to Vitamin K antagonists (VKA)

There is a potential for inadequate anticoagulation during the transition from Vaxato to VKA. Continuous adequate anticoagulation should be ensured during any transition to an alternate anticoagulant. It should be noted that Vaxato can contribute to an elevated INR.

In patients converting from Vaxato to VKA, VKA should be given concurrently until the INR is ≥ 2.0. For the first two days of the conversion period, standard initial dosing of VKA should be used followed by VKA dosing, as guided by INR testing. While patients are on both Vaxato and VKA the INR should not be tested earlier than 24 hours after the previous dose but prior to the next dose of Vaxato. Once Vaxato is discontinued INR testing may be done reliably at least 24 hours after the last dose (see sections 4.5 and 5.2).

Converting from parenteral anticoagulants to Vaxato

For patients currently receiving a parenteral anticoagulant, discontinue the parenteral anticoagulant and start Vaxato 0 to 2 hours before the time that the next scheduled administration of the parenteral medicinal product (e.g. low molecular weight heparins) would be due or at the time of discontinuation of a continuously administered parenteral medicinal product (e.g. intravenous unfractionated heparin).

Converting from Vaxato to parenteral anticoagulants

Give the first dose of parenteral anticoagulant at the time the next Vaxato dose would be taken.

Special populations Renal impairment

Limited clinical data for patients with severe renal impairment (creatinine clearance 15 - 29 ml/min) indicate that rivaroxaban plasma concentrations are significantly increased. Therefore, Vaxato is to be used with caution in these patients. Use is not recommended in patients with creatinine clearance < 15 ml/min (see sections 4.4 and 5.2).

No dose adjustment is necessary in patients with mild renal impairment (creatinine clearance 50 - 80 ml/min) or moderate renal impairment (creatinine clearance 30 - 49 ml/min) (see section 5.2).

Hepatic impairment

Vaxato is contraindicated in patients with hepatic disease associated with coagulopathy and clinically relevant bleeding risk including cirrhotic patients with Child Pugh B and C (see sections 4.3 and 5.2).

Elderly population

No dose adjustment (see sections 4.4 and 5.2)

The risk of bleeding increases with increasing age (see section 4.4).

Body weight

No dose adjustment (see sections 4.4 and 5.2)

Gender

No dose adjustment (see section 5.2)

Paediatric population

The safety and efficacy of Vaxato in children aged 0 to 18 years have not been established. No data are available. Therefore, Vaxato is not recommended for use in children below 18 years of age.

Method of administration Vaxato is for oral use.

The tablets can be taken with or without food (see sections 4.5 and 5.2).

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.