EU Risk Management Plan
For
Rivaroxaban Jubilant 2.5/10/15/20 mg film coated tablets

Part VI: Summary of the risk management plan

Summary of Risk Management Plan for Rivaroxaban Jubilant 2.5mg, 10mg, 15mg and 20mg film coated tablets

This is a summary of the risk management plan (RMP) for Rivaroxaban Jubilant 2.5mg, 10mg, 15mg and 20mg film coated tablets. The RMP details important risks of Rivaroxaban Jubilant, how these risks can be minimised, and how more information will be obtained about Rivaroxaban risks and uncertainties (missing information).

Rivaroxaban Jubilant 2.5mg, 10mg, 15mg and 20mg film coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Rivaroxaban Jubilant 2.5mg, 10mg, 15mg and 20 mg film coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of Rivaroxaban Jubilant 2.5mg, 10mg, 15mg and 20mg film coated tablets's RMP.

I. The medicine and what it is used for

Rivaroxaban Jubilant 2.5 mg film-coated tablets:

Rivaroxaban Jubilant tablets, 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.

RivaroxabanJubilant tablets, 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.

Rivaroxaban Jubilant 10 mg film-coated tablets:

Prevention of venous thromboembolism (VTE) in adult patients undergoing elective hip or knee replacement surgery.

Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

Rivaroxaban Jubilant 15 mg film-coated tablets:

Adults

Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack.

Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

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Paediatric population

Treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years and weighing from 30 kg to 50 kg after at least 5 days of initial parenteral anticoagulation treatment.

Rivaroxaban Jubilant 20 mg film-coated tablets:

Adults

Prevention of stroke and systemic embolism in adult patients with non-valvular atrial fibrillation with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75 years, diabetes mellitus, prior stroke or transient ischaemic attack.

Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.

Paediatric population

Treatment of venous thromboembolism (VTE) and prevention of VTE recurrence in children and adolescents aged less than 18 years and weighing more than 50 kg after at least 5 days of initial parenteral anticoagulation treatment.

Rivaroxaban Jubilant film coated tablets contains rivaroxaban as the active substance and it is given by oral route of administration.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Rivaroxaban Jubilant 2.5mg, 10mg, 15mg and 20mg film coated tablets, together with measures to minimise such risks for learning more about Rivaroxaban risks, are outlined below:

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute routine risk minimisation measures.

In the case of Rivaroxaban Jubilant 2.5mg, 10mg, 15mg and 20mg film coated tablets, these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below.

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In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment and signal management activity, as applicable, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

Routine pharmacovigilance activities beyond adverse reactions reporting, aggregate reports, and signal detection includes the proposed specific adverse reaction follow-up questionnaires for liver-related adverse events, and renal impairment/renal failure.

II.A List of important risks and missing information

Important risks of Rivaroxaban Jubilant 2.5mg, 10mg, 15mg and 20mg film coated tablets are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Rivaroxaban Jubilant 2.5mg, 10mg, 15mg and 20mg film coated tablets.

Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation.

Missing information refers to information on the safety of this medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

Summary of safety concerns	
Important identified risks	• Haemorrhage
Important potential risks	• Embryo-fetal toxicity
Missing information	• Remedial pro-coagulant therapy for excessive haemorrhage • Patients with atrial fibrillation (AF) and prosthetic heart valve

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product (Xarelto film coated tablets of Bayer AG).

Important Identified Risks: Haemorrhage	
Risk minimisation measures	<u>Routine risk minimisation measures:</u> SmPC: Section-4.3: Contraindications, 4.4: Special warnings and precautions for use, 4.8: Undesirable effects, 4.9: Overdose PI: section- 2, 3 and 4 Limited pack size Prescription only medicine

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	Additional risk minimisation measures: Educational material for prescribers Patient alert cards
Additional pharmacovigilance activities	None

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Rivaroxaban Jubilant 2.5mg, 10mg, 15mg and 20mg film coated tablets.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for Rivaroxaban Jubilant 2.5mg, 10mg, 15mg and 20mg film coated tablets.