Part VI: Summary of the risk management plan

Summary of risk management plan for MIREBAX film coated tablets (Rivaroxaban)

This is a summary of the risk management plan (RMP) for MIREBAX, film-coated tablets. The RMP details important risks of MIREBAX, film-coated tablets, how these risks can be minimised, and how more information will be obtained about MIREBAX, film-coated tablets risks and uncertainties (missing information).

MIREBAX, , film-coated tablets summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how MIREBAX, film-coated tablets should be used.

Important new concerns or changes to the current ones will be included in updates of MIREBAX's RMP.

I. The medicine and what it is used for

MIREBAX 2,5mg film-coated tablet 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. When 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. It contains Rivaroxaban as the active substance and it is given by oral route.

MIREBAX 10 mg film-coated tablet is indicated to prevent venous thromboembolism (VTE) in adult patients undergoing elective hip or kneereplacement surgery and also to treat deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevent of recurrentDVT and PE in adults. It contains Rivaroxaban as the active substance and it is given by oral route.

MIREBAX 15 and 20 mg film-coated tablet are authorized for adults to prevent 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. It is authorized also for treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults. MIREBAX 15 and 20 mg film-coated tablets are authorized also for paediatric population to treat venous thromboembolism (VTE) and to prevent VTE recurrence in children and adolescents aged less than 18 years and weighing from 30 kg to 50 kg (15 mg) or more than 50 kg (20 mg) after at least 5 days of initial parenteral anticoagulation treatment. They contain Rivaroxaban as the active substance and they are given by oral route

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

Important risks of MIREBAX, 20 mg, 15 mg 10mg and 2.5mg film-coated tablets, together with measures to minimise such risks and the proposed studies for learning more about MIREBAX 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.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed so that immediate action can be taken as necessary. Together, these measures constitute routine risk minimisation measures.

In the case of Mirebax these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below.

If important information that may affect the safe use of MIREBAX is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks for MIREBAX are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. 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 MIREBAX. 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 the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

List of important risks and missing information	
Important identified risks	– Haemorrhage
Important potential risks	– Embryo-foetal toxicity
Missing information	– Remedial pro-coagulant therapy for excessive haemorrhage

List of important risks and missing information	
	– Patients with atrial fibrillation (AF) and a prosthetic heart valve

II.B Summary of important risks

Important identified risk: Haemorrhage	
Risk minimisation measures	Routine risk minimisation measures: – SmPC sections 4.2, 4.3, 4.4, 4.6, 4.8, 4.9 and 5.3. – PL sections 2 and 4. – Prescription-only medicine. – Limited pack sizes. Additional risk minimisation measures: – Educational material for prescribers. – Patient alert cards.
Important potential risk: Embryo-foetal toxicity	
Risk minimisation measures	Routine risk minimisation measures: – SmPC sections 4.3, 4.6 and 5.3 and related PL sections. – Prescription-only medicine. – Limited pack sizes. Additional risk minimisation measures: None
Missing information: Remedial pro-coagulant therapy for excessive haemorrhage	
Risk minimisation measures	Routine risk minimisation measures: – SmPC section 4.9 and related PL sections. – Prescription-only medicine. – Limited pack sizes. Additional risk minimisation measures: None
Missing information: Patients with atrial fibrillation (AF) and a prosthetic heart valve	
Risk minimisation measures	Routine risk minimisation measures: – SmPC section 4.4 and related PL sections. – Prescription-only medicine. – Limited pack sizes Additional risk minimisation measures: 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 MIREBAX.

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

There are no studies required for MIREBAX.