Part VI: Summary of the risk management plan

Summary of risk management plan for Risagal (Rivaroxaban)

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

Risagal 's summary of product characteristics (SPC) and its patient Information Leaflet (PIL) give essential information to healthcare professionals and patients on how Risagal should be used.

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

I. The medicine and what it is used for

Risagal is authorised for (see SPC for the full indication):

2.5 mg film-coated tablets:

> Rivaroxaban 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.
>
> Rivaroxaban 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.

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. (See section 4.4 for haemodynamically unstable PE patients.)

15 mg film-coated tablets:

> 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 $\geqslant$ 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.

20 mg film-coated tablets:

> 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 $\geqslant$ 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.

It contains rivaroxaban as the active substance, and it is given by oral administration.

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

Important risks of Risagal together with measures to minimise such 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 Risagal these measures are supplemented with additional risk minimisation measures mentioned under relevant important risks, below.

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

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

II.A List of important risks and missing information

Important risks of Risagal 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 Risagal. 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 • 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: Information presented in the following SmPC sections: 4.3, 4.4, 4.5, 4.8 and 4.9. Other: Limited pack size

	Legal status of the product: Prescription-only medicine. Additional risk minimisation measures: - Prescriber guide - Patient Alert Card
Additional Pharmacovigilance activities	None

Important Potential risk: Embryo-foetal toxicity	
Risk minimisation measures	Routine risk minimisation measures: Information presented in the following SmPC sections: 4.3, 4.6 and 5.3. Other: Limited pack size Legal status of the product: Prescription-only medicine. Additional risk minimisation measures: None
Additional Pharmacovigilance activities	None

Missing information: Remedial pro-coagulant therapy for excessive haemorrhage	
Risk minimisation measures	Routine risk minimisation measures: Information presented in the following SmPC section 4.9. Other: Limited pack size Legal status of the product: Prescription-only medicine. Additional risk minimisation measures: None
Additional Pharmacovigilance activities	None

Missing information: Patients with atrial fibrillation (AF) and a prosthetic heart valve	
Risk minimisation measures	Routine risk minimisation measures:

	Information presented in the following SmPC section 4.4. Other: Limited pack size Legal status of the product: Prescription-only medicine. Additional risk minimisation measures: None
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 Risagal.

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

There are no studies required for Risagal.