Part VI: Summary of the risk management plan

Summary of risk management plan for Odelo (rivaroxaban)

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

Odelo's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Odelo should be used.

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

I. The medicine and what it is used for

Odelo 2.5 mg film-coated tablets are authorised:

- co-administered with acetylsalicylic acid (ASA) alone or with ASA plus clopidogrel or ticlopidine, for the prevention of atherothrombotic events in adult patients after an acute coronary syndrome (ACS) with elevated cardiac biomarkers.
- co-administered with acetylsalicylic acid (ASA), 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.

Odelo 10 mg film-coated tablets are authorised for:

- 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.

Odelo 15 mg, 20 mg film-coated tablets are authorised for:

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

(see SmPC for the full indication).

It contains rivaroxaban as the active substance, and it is given orally.

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

Important risks of Odelo, together with measures to minimise such risks and the proposed studies for learning more about Odelo's 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 Odelo, 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 Odelo is not yet available, it is listed under "missing information" below.

II.A List of important risks and missing information

Important risks of Odelo 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 Odelo. 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-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

Important identified risk: Haemorrhage	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.3., 4.4., 4.5., 4.6., 4.8. and 4.9. Recommendation for adequate clinical surveillance and laboratory testing of haemoglobin/haematocrit to detect occult bleeding and quantify the clinical relevance of overt bleeding is included in SmPC sections 4.4 and 4.8. Recommendation for careful monitoring of several sub-groups of patients at increased risk of bleeding for signs and symptoms of bleeding complications and anaemia after initiation of treatment is included in SmPC section 4.4. Recommendation for measuring rivaroxaban levels with a calibrated quantitative anti-factor Xa assay in exceptional situations where knowledge of rivaroxaban exposure may help to inform clinical decisions, e.g., overdose and emergency surgery is included in SmPC section 4.4. Recommendation for considering the pharmacokinetic profile of rivaroxaban in patients with concurrent use of rivaroxaban and neuraxial (epidural/spinal) anaesthesia or spinal puncture is included in SmPC section 4.4. Dosing recommendations before and after invasive procedures and surgical intervention are included in SmPC section 4.4. Advice on management of bleeding is provided in SmPC section 4.9. PL section 2, 3 and 4. Prescription Only Medicine Additional risk minimisation measures: Prescriber Guide Patient Alert Card

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 Odelo.

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

There are no studies required for Odelo.