Part VI: Summary of the risk management plan

Summary of risk management plan for Anagrelide Bluefish

This is a summary of the risk management plan (RMP) for Anagrelide Bluefish. The RMP details important risks of Anagrelide Bluefish, which can be minimized through routine pharmacovigilance activities. Data on missing information will be gathered.

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

VI.1. The medicine and what it is used for

Anagrelide Bluefish is indicated for the reduction of elevated platelet counts in at risk essential thrombocythaemia (ET) patients who are intolerant to their current therapy or whose elevated platelet counts are not reduced to an acceptable level by their current therapy.

Each hard capsule contains anagrelide hydrochloride as the active substance and is administered orally in two divided doses (0.5 mg/dose).

VI.2. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Anagrelide Bluefish, together with measures to minimise such risks, are outlined below.

Important identified risks

Safety concerns	**Routine risk minimization measures**
Cardiac events (QT prolongation, ventricular tachycardia, cardiomyopathy, cardiomegaly and congestive heart failure)	1. Mentioned in SmPC: • Section 4.4. Special warning and precautions for use • Section 4.8. Undesirable effects 2. Mentioned in package leaflet 3. Prescription only medicine
Drug interaction with inhibitors of platelets aggregation (acetyl salicylic acid)	1. Mentioned in SmPC: • Section 4.4 Special warnings and precautions for use • Section 4.5 Interaction with other medicinal products and other forms of interaction 2. Mentioned in package leaflet 3. Prescription only medicine
Use in patients with moderate or severe hepatic impairment	1. Mentioned in the SmPC: • Section 4.2 Posology and method of administration • Section 4.3 Contraindications • Section 4.4 Special warnings and precautions 2. Mentioned in package leaflet 3. Prescription-only medicine

Safety concerns	Routine risk minimization measures
Use in patients with moderate or severe renal impairment (creatinine clearance < 50 ml/min)	1. Mentioned in the SmPC: • Section 4.2 Posology and method of administration • Section 4.3 Contraindications • Section 4.4 Special warnings and precautions for use 2. Mentioned in package leaflet 3. Prescription-only medicine
Pulmonary hypertension	1. Mentioned in the SmPC: • Section 4.4 Special warnings and precautions for use • Section 4.8 Undesirable effects 2. Mentioned in package leaflet 3. Prescription-only medicine

Important potential risks

Safety concerns	Risk minimization measures
Benign or malignant neoplasms (including myelofibrosis)	1. Mentioned in SmPC: • Section 4.4 Special warnings and precautions for use 2. Mentioned in package leaflet 3. Prescription only medicine
Lack of efficacy/Thrombo-haemorrhagic events	1. Mentioned in SmPC: • Section 4.4 Special warnings and precautions for use 2. Mentioned in package leaflet 3. Prescription only medicine
Interstitial lung disease	1. Mentioned in SmPC: • Section 4.8 Undesirable effects 2. Mentioned in package leaflet 3. Prescription only medicine

Missing information

If important information that may affect the safe use of Anagrelide Bluefish is not yet available, it is listed under ‘missing information’ below.

VI.2.1. List of important risks and missing information

Important risks of Anagrelide Bluefish are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered orally. 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 Anagrelide Bluefish. 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.

List of important risks and missing information	
Important identified risks	• Cardiac events (QT prolongation, ventricular tachycardia, cardiomyopathy, cardiomegaly and congestive heart failure) • Drug interaction with inhibitors of platelets aggregation (acetyl salicylic acid) • Use in patients with moderate or severe hepatic impairment • Use in patients with moderate or severe renal impairment (creatinine clearance < 50 ml/min) • Pulmonary hypertension
Important potential risks	• Benign or malignant neoplasms (including myelofibrosis) • Lack of efficacy/Thrombo-haemorrhagic events • Interstitial lung disease
Missing information	• Use in paediatric population • Exposure during pregnancy and lactation • Effects on fertility

VI.2.2. Summary of important risks

The safety information in the proposed product information is aligned with the reference medicinal product Xagrid®.

VI.2.3. Post-authorisation development plan

Not applicable.