Part VI: Summary of the risk management plan

Summary of risk management plan for Anagrelide 0.5 mg hard capsules (Anagrelide as anagrelide hydrochloride)

This is a summary of the risk management plan (RMP) for Anagrelide 0.5 mg hard capsules. The RMP details important risks of Anagrelide 0.5 mg hard capsules, how these risks can be minimised, and how more information will be obtained about Anagrelide 0.5 mg hard capsules risks and uncertainties (missing information).

Anagrelide 0.5 mg hard capsules summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Anagrelide 0.5 mg hard capsules should be used.

Important new concerns or changes to the current ones will be included in updates of Anagrelide 0.5 mg hard capsules RMP.

I. The medicine and what it is used for

Anagrelide 0.5 mg hard capsules 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.

An at risk patient

An at risk essential thrombocythaemia patient is defined by one or more of the following features:

- >60 years of age or
- a platelet count > 1000 x 10^9/l or
- A history of thrombo-haemorrhagic events.

Anagrelide 0.5 mg hard capsules contains anagrelide (as anagrelide hydrochloride) as the active substance and given orally.

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

Important risks of Anagrelide 0.5 mg hard capsules, together with measures to minimise such risks and the proposed studies for learning more about Anagrelide 0.5 mg hard capsules risks, are outlined below.

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

II.A List of important risks and missing information

Important risks Anagrelide 0.5 mg hard capsules 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 Anagrelide 0.5 mg hard capsules. 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).

Important identified risks	• None
Important potential risks	• None
Missing Information	• None

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II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

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 authorization or specific obligation of Anagrelide 0.5 mg hard capsules.

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

There are no studies required for Anagrelide 0.5 mg hard capsules as post-authorisation development plan.

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