Part VI: Summary of the risk management plan

Summary of risk management plan for Davunfite 1 mg, 2 mg 3 mg and 4 mg hard capsules.

This is a summary of the risk management plan (RMP) for Davunfite 1 mg, 2 mg 3 mg and 4 mg hard capsules. The RMP details important risks Davunfite 1 mg, 2 mg 3 mg and 4 mg hard capsules, how these risks can be minimised, and how more information will be obtained about Davunfite 1 mg, 2 mg 3 mg and 4 mg hard capsules risks and uncertainties (missing information).

Davunfite 1 mg, 2 mg 3 mg and 4 mg hard capsules ´s summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Davunfite 1 mg, 2 mg 3 mg and 4 mg hard capsules should be used.

Important new concerns or changes to the current ones will be included in updates of Davunfite 1 mg, 2 mg 3 mg and 4 mg hard capsule's RMP.

I. The medicine and what it is used for

Davunfite 1 mg, 2 mg 3 mg and 4 mg hard capsules are authorised for the following indications:

- Davunfite in combination with bortezomib and dexamethasone is indicated in the treatment of adult patients with multiple myeloma who have received at least one prior treatment regimen including lenalidomide.
- Davunfite in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.

It contains pomalidomide as the active substance and is given orally.

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

Important risks of Davunfite 1 mg, 2 mg 3 mg and 4 mg hard capsules, together with measures to minimise such risks and the proposed studies for learning more about Davunfite 1 mg, 2 mg 3 mg and 4 mg hard capsules ´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 Davunfite, 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*.

II.A List of important risks and missing information

Important risks of Davunfite 1 mg, 2 mg 3 mg and 4 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 Davunfite 1 mg, 2 mg 3 mg and 4 mg hard capsules tablets. 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);

Summary of safety concerns	
Important identified risks	• Teratogenicity • Severe infection due to neutropenia and pancytopenia • Thrombocytopenia and bleeding • Cardiac failure • Non-Melanoma skin cancer
Important potential risks	• Other Second primary malignancies • Cardiac arrhythmia
Missing information	None

II.B Summary of important risks

Summary of important risk that have corresponding additional risk minimisation activities are:

Important identified risk: **Teratogenicity**	
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.3 and 4.4; PL sections 2 and 4. Additional risk minimisation measures: Pregnancy Prevention Programme. -Educational Healthcare Professional's Kit -Educational Brochures for patients -Patient Card or equivalent tool -Risk Awareness Forms Monitoring of implementation and compliance of the PPP
Important identified risk: **Thrombocytopenia and bleeding**	
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.2, 4.4 and 4.8; PL sections 2 and 4.

	Additional risk minimisation measures: - Educational Brochures for patients - HCP Educational Materials
Important identified risk: **Cardiac failure**	
Risk minimisation measures	Routine risk minimisation measures: SmPC sections 4.4 and 4.8; PL sections 2 and 4. Additional risk minimisation measures: - HCP additional educational materials.

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 Davunfite 1 mg, 2 mg 3 mg and 4 mg hard capsules.

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

There are no studies required for Davunfite 1 mg, 2 mg 3 mg and 4 mg hard capsules.