

## **Summary of risk management plan for idarubicin**

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

Zavedos's SmPC and its package leaflet give essential information to healthcare professionals and patients on how idarubicin should be used.

### **I. The Medicine and What It Is Used For**

Zavedos is authorised for treatment of AML, ALL and advanced breast cancer (see SmPC for the full indication). It contains idarubicin as the active substance and it is given by oral and intravenous routes of administration.

### **II. Risks Associated With the Medicine and Activities to Minimise or Further Characterise the Risks**

There were no important risks identified for Zavedos.

In general, 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 events is collected continuously and regularly analysed, including PSUR assessment 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 are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely used. 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 product. 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).

No important risks and missing information have been identified for Zavedos.

**Table 1. List of important risks and missing information**

Important identified risks	None
Important potential risks	None
Missing information	None

## **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 authorisation or specific obligation of Zavedos.

### **II.C.2 Other Studies in Post-Authorisation Development Plan**

There are no studies required for Zavedos.