

# Mercaptopurin Orion

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## PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

### ***Summary of risk management plan for Mercaptopurin Orion (mercaptopurine)***

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

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

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

### **I. The medicine and what it is used for**

Mercaptopurin Orion is authorised for treatment of inflammatory bowel disease (see SmPC for the full indication). It contains mercaptopurine as the active substance and it is given by mouth.

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

Important risks of Mercaptopurin Orion, together with measures to minimise such risks and the proposed studies for learning more about Mercaptopurin Orion'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.

#### ***II.A List of important risks and missing information***

This product has no safety concerns requiring additional pharmacovigilance actions or additional risk minimisation activities.

#### ***II.B Summary of important risks***

Safety concerns are adequately addressed in the product information.

#### ***II.C Post-authorisation development plan***

There are no studies required for Mercaptopurin Orion.