

## **PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN**

### **Summary of risk management plan for Colchicine Strides 0.5 mg Tablets:**

Colchicine Strides contains the active substance Colchicine and is used to prevent or treat a gout attack. The concentration of uric acid in the blood is increased when having gout. This can lead to the formation of crystals of uric acid in the synovial fluid. Colchicine inhibits the inflammation that occurs as a result.

This is a summary of the risk management plan (RMP) for Colchicine Strides 0.5 mg Tablets. The RMP details important risks of Colchicine, how these risks can be minimized and how more information will be obtained about Colchicine risks and uncertainties (missing information). Colchicine summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Colchicine should be used.

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

Colchicine is indicated for the short-term treatment of acute gout, known as gout attacks in adults. Colchicine is also used for the prevention of recurrent gout.

Colchicine is indicated in Familial Mediterranean Fever for prevention of fever attacks and amyloidosis (abnormal accumulation of proteins in tissues and organs).

#### **II. Risks associated with the medicine and activities to minimize or further characterize the risks:**

There are no important identified risks, important potential risks and missing information identified for Colchicine Strides 0.5 mg Tablets.

Measures to minimize the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the summary of product characteristics (SmPC) addressed to patients and healthcare professionals.
- Important advice on the medicine's packaging.
- The medicine's legal status - the way a medicine is supplied to the patient (e.g. with or without Prescription) can help to minimize its risks.

Together, these measures constitute routine risk minimization measures.

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

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

Important risks can be regarded as identified or potential. Identified risks are concerns for which there is enough proof of a link with the use of colchicine. 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).

### **Table 2: Summary of safety concerns**

This is not applicable as there are no mandatory important identified risks, important potential risks and missing information identified for Colchicine Strides 0.5 mg Tablets.

## **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 colchicine.

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

There are no studies required for colchicine.