

Part VI: Summary of the risk management plan

Summary of risk management plan for Firekol (roflumilast) film-coated tablets

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

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

I. The medicine and what it is used for

Firekol is authorised for maintenance treatment of severe chronic obstructive pulmonary disease (COPD) (FEV₁ post-bronchodilator less than 50% predicted) associated with chronic bronchitis in adult patients with a history of frequent exacerbations as add on to bronchodilator treatment.

(see SmPC for the full indication)

It contains roflumilast as the active substance, and it is given orally.

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

Important risks of Firekol, together with measures to minimise such risks and the proposed studies for learning more about Firekol risks, are outlined below.

Measures to minimise the risks identified for medicinal products are:

- 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 so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of Firekol is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Firekol 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 Firekol. 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	<ul style="list-style-type: none"> • Weight decrease • Diarrhoea • Psychiatric disorders (depression, suicidal ideation and behaviour)
Important potential risks	<ul style="list-style-type: none"> • Malignant tumours • Infections • Major cardiovascular events
Missing information	<ul style="list-style-type: none"> • Long-term treatment

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 Firekol.

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

There are no studies required for Firekol.