

Part VI: Summary of the risk management plan

Summary of risk management plan for DAFLON (Micronized Purified Flavonoid Fraction (MPFF))

This is a summary of the risk management plan (RMP) for DAFLON.

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

I. The medicine and what it is used for

DAFLON's is authorised for *Symptoms caused by venous insufficiency; capillary fragility* (Sintomi attribuibili a insufficienza venosa; stati di fragilità capillare) and *Symptomatic treatment of acute haemorrhoidal crisis* (Trattamento sintomatico della crisi emorroidaria acuta) (see SmPC for the full indication). It contains Micronized Purified Flavonoid Fraction as the active substance and it is given by oral route.

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

II.A List of important risks and missing information

Important risks of DAFLON are risks that need special risk management activities to further investigate or minimise 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 sufficient proof of a link with the use of DAFLON. 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).

List of important risks and missing information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable.

II.C Post-authorisation development plan

Not applicable.

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 DAFLON.

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

There are no studies required for DAFLON.