

Part VI: Summary of the risk management plan

Summary of risk management plan for Apremilast Day Zero 10, 20 and 30 mg film-coated tablets

This is a summary of the risk management plan (RMP) for Apremilast Day Zero. The RMP details important risks of Apremilast Day Zero and how more information will be obtained about Apremilast Day Zero risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Apremilast Day Zero's RMP.

I. The medicine and what it is used for

Apremilast Day Zero is authorised for the following indications:

- Apremilast Day Zero, alone or in combination with Disease Modifying Antirheumatic Drugs (DMARDs), is indicated for the treatment of active psoriatic arthritis (PsA) in adult patients who have had an inadequate response or who have been intolerant to a prior DMARD therapy (see section 5.1).
- Apremilast Day Zero is indicated for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or psoralen and ultraviolet-A light (PUVA).
- Apremilast Day Zero is indicated for the treatment of adult patients with oral ulcers associated with Behçet's disease (BD) who are candidates for systemic therapy.

It contains apremilast as the active substance and is given orally.

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

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

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 Apremilast Day Zero is not yet available, it is listed under 'missing information' below

II.A List of important risks and missing information

Important risks of Apremilast Day Zero 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 Apremilast Day Zero. 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 | Serious events of hypersensitivity Suicidality Serious events of depression |
| Important potential risks | Vasculitis Malignancies Serious events of anxiety and nervousness Serious infections including opportunistic infections and transmissions of infections through live vaccines MACE (major cardiovascular event) and tachyarrhythmia Prenatal embryo-fetal loss and delayed fetal development (reduced ossification and fetal weight) in pregnant women exposed to apremilast. |
| Missing information | Long-term safety |

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 Apremilast Day Zero.

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

There are no studies required for Apremilast Day Zero.