



## **Part VI: Summary of the risk management plan**

RMP Part VI is valid for all products in this RMP: Apremilast Devatis (Apremilast 10 mg, 20 mg, 30 mg filmcoated tablets)

# Summary of risk management plan for Apremilast Devatis (Apremilast 10 mg, 20 mg, 30 mg filmcoated tablets)

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

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

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

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

Apremilast Devatis is authorised for:

### Psoriatic arthritis

- Apremilast, 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.

### Psoriasis

- Apremilast 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).

### Paediatric psoriasis

- Apremilast is indicated for the treatment of moderate to severe plaque psoriasis in children and adolescents from the age of 6 years and weighing at least 20 kg who are candidates for systemic therapy.

### Behçet's disease

- Apremilast 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 it is given orally.

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

Important risks of Apremilast Devatis, together with measures to minimise such risks and the proposed studies for learning more about Apremilast Devatis'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 Devatis is not yet available, it is listed under 'missing information' below.

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

Important risks of Apremilast Devatis 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 Devatis. 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);

<b>List of important risks and missing information</b>	
Important identified risks	<ul style="list-style-type: none"> <li>• Serious events of hypersensitivity</li> <li>• Suicidality</li> <li>• Serious events of depression</li> </ul>
Important potential risks	<ul style="list-style-type: none"> <li>• Vasculitis</li> <li>• Malignancies</li> <li>• Serious events of anxiety and nervousness</li> <li>• Serious infections including opportunistic infections and transmission of infections through live vaccines</li> <li>• Major adverse cardiac event (MACE) and tachyarrhythmia</li> <li>• Prenatal embryo-fetal loss and delayed fetal development</li> </ul>

<b>List of important risks and missing information</b>	
	(reduced ossification and fetal weight) in pregnant women exposed to apremilast
Missing information	<ul style="list-style-type: none"><li>• Long-term safety</li></ul>

### ***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 Devatis.

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

There are no studies which are conditions of the marketing authorisation or specific obligation of Apremilast Devatis.