Summary of risk management plan for Apremilast STADA, Apremilast STADA Arzneimittel AG, Apremilast STADA Nordic 30 mg & 10 mg + 20 mg + 30 mg filmdragerade tabletter (Apremilast)

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

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

Important new concerns or changes to the current ones will be included in updates of Apremilast STADA's/ Apremilast STADA Arzneimittel AG's/ Apremilast STADA Nordic's RMP.

I. The medicine and what it is used for

Apremilast STADA/ Apremilast STADA Arzneimittel AG/ Apremilast STADA Nordic is authorised 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; 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); and for the treatment of adult patients with oral ulcers associated with Behçet's disease (BD) who are candidates for systemic therapy (see SmPC for the full indication). 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 STADA/ Apremilast STADA Arzneimittel AG/ Apremilast STADA Nordic, together with measures to minimise such risks and the proposed studies for learning more about Apremilast STADA's/ Apremilast STADA Arzneimittel AG's/ Apremilast STADA Nordic'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 STADA/ Apremilast STADA Arzneimittel AG/ Apremilast STADA Nordic is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Apremilast STADA/ Apremilast STADA Arzneimittel AG/ Apremilast STADA Nordic 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 STADA/ Apremilast STADA Arzneimittel AG/ Apremilast STADA Nordic. 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	• 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 transmission of infections through live vaccines • Major adverse cardiac event (MACE) 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 STADA/ Apremilast STADA Arzneimittel AG/ Apremilast STADA Nordic.

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

There are no studies required for Apremilast STADA/ Apremilast STADA Arzneimittel AG/ Apremilast STADA Nordic.