Summary of risk management plan for apomorphine

This is a summary of the risk management plan (RMP) for APO-go PFS, APO-go PEN, APO-go Ampoules and APO-go POD. The RMP details important risks of apomorphine, how these risks can be minimised, and how more information will be obtained about apomorphine's risks and uncertainties (missing information).

The summary of product characteristics (SmPC) and package leaflets give essential information to healthcare professionals and patients on how APO-go PFS, APO-go PEN, APO-go Ampoules and APO-go POD should be used.

I. The medicine and what it is used for

APO-go PFS, APO-go PEN, APO-go Ampoules and APO-go POD are authorised for treatment of motor fluctuations ('on-off' phenomena) in patients with Parkinson’s disease which are not sufficiently controlled by oral anti-Parkinson medication (see SmPC for the full indication). They contain apomorphine as the active substance and are given by continuous subcutaneous infusion and/or intermittent injection.

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

Important risks of APO-go PFS, APO-go PEN, APO-go Ampoules and APO-go POD, together with measures to minimise such risks and the proposed studies for learning more about APO-go PFS, APO-go PEN, APO-go Ampoules and APO-go POD’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 above measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate actions can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of APO-go PFS, APO-go PEN, APO-go Ampoules and APO-go POD are not yet available, this is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of APO-go PFS, APO-go PEN, APO-go Ampoules and APO-go POD 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 APO-go PFS, APO-go PEN, APO-go Ampoules and APO-go POD. 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	None
Important potential risks	Dopamine dysregulation syndrome Punding Dopamine agonist withdrawal syndrome
	Use in pregnancy
Missing information	Use in lactation

II.B Summary of important risks Module SVII is applicable:

Important potential risks	
Dopamine dysregulation syndrome	
Evidence for linking the risk to the medicine	Post marketing experience
Risk factors and risk groups	Unknown
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4 PL section 2 Additional risk minimisation measures: No additional risk minimisation measures
Punding	
Evidence for linking the risk to the medicine	Post marketing experience

Risk factors and risk groups	Unknown
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4 PL section 2 Additional risk minimisation measures: No additional risk minimisation measures

Dopamine agonist withdrawal syndrome	
Evidence for linking the risk to the medicine	Post marketing experience
Risk factors and risk groups	Parkinson's Disease patients who suffer from impulse control disorders and/or Dopamine Dysregulation Syndrome may be more at risk of Dopamine Agonist Withdrawal Syndrome.
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.4 PL section 2 Additional risk minimisation measures: No additional risk minimisation measures
Use in pregnancy	
Evidence for linking the risk to the medicine	There is no experience of apomorphine use in human pregnancy
Risk factors and risk groups	Unknown

Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.6 PL section 2 Additional risk minimisation measures: No additional risk minimisation measures
Missing information	
Use in lactation	
Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.6 PL section 2 Additional risk minimisation measures:
	No additional risk minimisation measures

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 APO-go PFS, APO-go PEN, APO-go Ampoules and APO-go POD.

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

There are no studies required for APO-go PFS, APO-go PEN, APO-go Ampoules and APO-go POD.