Part VI: Summary of the risk management plan - 50 mg and 250 mg

Summary of risk management plan for Primidon Afortas (Primidone)

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

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

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

I. The medicine and what it is used for

Primidon Afortas is authorised for the management of generalized tonic-clonic seizures and focal aware/impaired awareness seizure, focal aware motor seizures, of focal myoclonic seizures and focal behaviour arrest seizures, generalized absence seizures and essential tremor (see SmPC for the full indication).

It contains Primidone as the active substance and it is given by oral route of administration.

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

Important risks of Primidon Afortas, together with measures to minimise such risks and the proposed studies for learning more about Primidon Afortas’s risks, are outlined below.

Measures to minimize the risks identified for medicinal products are:

- 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 authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* 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.

II.A List of important risks and missing information

Important risks of Primidon Afortas 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 Primidon Afortas. 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	Bone disorders Suicidal ideation Withdrawal syndrome Drug reaction with eosinophilia and systemic symptoms (DRESS)
Important potential risks	Severe skin disorders Major Congenital Malformations (MCM) Neurodevelopmental Disorders (NDD)
Missing information	None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product (Mysoline).

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 Primidon Afortas.

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

There are no studies required for Primidon Afortas.

Part VI: Summary of the risk management plan - 125 mg

Summary of risk management plan for Primidon Afortas (Primidone):

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

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

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

I. The medicine and what it is used for

Primidon Afortas is authorised for the management of generalized tonic-clonic seizures and focal aware/impaired awareness seizure, focal aware motor seizures, of focal myoclonic seizures and focal behaviour arrest seizures, generalized absence seizures and essential tremor (see SmPC for the full indication).

It contains Primidone as the active substance and it is given by oral route of administration.

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

Important risks of Primidon Afortas, together with measures to minimise such risks and the proposed studies for learning more about Primidon Afortas’s risks, are outlined below.

Measures to minimize the risks identified for medicinal products are:

- 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 authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

II.A List of important risks and missing information

Important risks of Primidon Afortas 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 Primidon Afortas. 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	Bone disorders Suicidal ideation Withdrawal syndrome Drug reaction with eosinophilia and systemic symptoms (DRESS)
Important potential risks	Severe skin disorders Major Congenital Malformations (MCM) Neurodevelopmental Disorders (NDD)
Missing information	None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product (Mysoline).

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 Primidon Afortas.

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

There are no studies required for Primidon Afortas.