Part VI: Summary of the risk management plan

Summary of risk management plan for Brivaracetam Zentiva (Brivaracetam)

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

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

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

I. The medicine and what it is used for

Brivaracetam Zentiva is authorised as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy (See SmPC for the full indication). It contains Brivaracetam as the active substance and it is given by oral administration.

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

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

II.A List of important risks and missing information

Important risks of Brivaracetam Zentiva 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 Brivaracetam Zentiva. 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	• Suicidality (class label for anticonvulsant products)
Important identified risks	• None
Missing information	• Data during pregnancy and lactation • Long-term effects on growth, endocrine function or sexual maturation, neurodevelopment, cognitive and psychomotor development in pediatric patients

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 the Applicant's Brivaracetam Zentiva.

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

There are no studies required for Applicant's Brivaracetam Zentiva.

Summary of risk management plan for Gemgerta (Brivaracetam)

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

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

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

I. The medicine and what it is used for

Gemgerta is authorised as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy (See SmPC for the full indication). It contains Brivaracetam as the active substance and it is given by oral administration.

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

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

II.A List of important risks and missing information

Important risks of Gemgerta 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 Gemgerta. 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	• Suicidality (class label for anticonvulsant products)
Important identified risks	• None
Missing information	• Data during pregnancy and lactation • Long-term effects on growth, endocrine function or sexual maturation, neurodevelopment, cognitive and psychomotor development in pediatric patients

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 the Applicant's Gemgerta.

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

There are no studies required for Applicant's Gemgerta.

Summary of risk management plan for Brivaracetam Adalvo (Brivaracetam)

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

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

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

I. The medicine and what it is used for

Brivaracetam Adalvo is authorised as adjunctive therapy in the treatment of partial onset seizures with or without secondary generalisation in adults, adolescents and children from 2 years of age with epilepsy (See SmPC for the full indication). It contains Brivaracetam as the active substance and it is given by oral administration.

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

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

II.A List of important risks and missing information

Important risks of Brivaracetam Adalvo 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 Brivaracetam Adalvo. 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	• Suicidality (class label for anticonvulsant products)
Important identified risks	• None
Missing information	• Data during pregnancy and lactation • Long-term effects on growth, endocrine function or sexual maturation, neurodevelopment, cognitive and psychomotor development in pediatric patients

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 the Applicant's Brivaracetam Adalvo.

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

There are no studies required for Applicant's Brivaracetam Adalvo.