PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN BY PRODUCT: RISPERDAL

Summary of Risk Management Plan for RISPERDAL (Oral Risperidone)

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

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

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

I. The Medicine and What It Is Used For

RISPERDAL is authorized for the following (see SmPC for the full indication):

- Treatment of schizophrenia
- Treatment of moderate to severe manic episodes associated with bipolar disorders
- Short-term treatment (up to 6 weeks) of persistent aggression in patients with moderate to severe Alzheimer's dementia unresponsive to nonpharmacological approaches and when there is a risk of harm to self or others
- Short-term symptomatic treatment (up to 6 weeks) of persistent aggression in conduct disorder in children from the age of 5 years and adolescents with subaverage intellectual functioning or mental retardation, in whom the severity of aggressive or other disruptive behaviors requires pharmacologic treatment

RISPERDAL contains risperidone as the active substance, and it is given by mouth as a tablet to be swallowed, a tablet that dissolves in the mouth, or as a liquid.

II. Risks Associated With the Medicine and Activities to Minimize or Further Characterize the Risks

Important risks of RISPERDAL, together with measures to minimize such risks and the proposed studies for learning more about RISPERDAL's risks, are outlined below.

Measures to minimize 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 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 (eg, 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 analyzed, including assessment in Periodic Benefit Risk Evaluation Reports/Periodic Safety Update Reports (PBRERs/PSURs), 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 RISPERDAL are risks that need special risk management activities to further investigate or minimize 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 RISPERDAL. 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.

List of Important Risks and Missing Information for RISPERDAL	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B. Summary of Important Risks

Not applicable.

II.C. Postauthorization Development Plan

II.C.1. Studies Which are Conditions of the Marketing Authorization

There are no studies which are conditions of the marketing authorization or a specific obligation for RISPERDAL.

II.C.2. Other Studies in Postauthorization Development Plan

There are no studies required for RISPERDAL.

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN BY PRODUCT: RISPERDAL CONSTA

Summary of Risk Management Plan for RISPERDAL CONSTA (Risperidone Long-acting Injection)

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

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

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

I. The Medicine and What It Is Used For

RISPERDAL CONSTA is authorized for the maintenance treatment of schizophrenia in patients currently stabilized with oral antipsychotics (see SmPC for the full indication). It contains risperidone as the active substance, and it is given as an intramuscular injection (25, 37.5, and 50 mg powder and solvent for prolonged-release suspension), administered by a health care professional.

II. Risks Associated With the Medicine and Activities to Minimize or Further Characterize the Risks

Important risks of RISPERDAL CONSTA, together with measures to minimize such risks and the proposed studies for learning more about RISPERDAL CONSTA's risks, are outlined below.

Measures to minimize 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 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 (eg, 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 analyzed, including assessment in Periodic Benefit Risk Evaluation Reports/Periodic Safety Update Reports (PBRERs/PSURs), 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 RISPERDAL CONSTA are risks that need special risk management activities to further investigate or minimize 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 RISPERDAL CONSTA. 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.

List of Important Risks and Missing Information for RISPERDAL CONSTA	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B. Summary of Important Risks

Not applicable.

II.C. Postauthorization Development Plan

II.C.1. Studies Which are Conditions of the Marketing Authorization

There are no studies which are conditions of the marketing authorization or a specific obligation for RISPERDAL CONSTA.

II.C.2. Other Studies in Postauthorization Development Plan

There are no studies required for RISPERDAL CONSTA.