Pramipexole Stada

18.10.2013, Version V01

PUBLIC SUMMARY OF RISK MANAGEMENT PLAN

VI.2 Elements for a Public Summary

Pramipexole STADA 0,088 mg tablets
Pramipexole STADA 0,18 mg tablets
Pramipexole STADA 0,35 mg tablets
Pramipexole STADA 0,7 mg tablets
Pramipexole STADA 1,1 mg tablets

VI.2.1 Overview of disease epidemiology

Parkinson's Disease (PD), also known as Morbus Parkinson, is a slowly proceeding, neurological disease that mainly affects older people. Brain cells are dying and lead to a lack of the chemical messenger dopamine, a so called neurotransmitter. Restless-Legs-Syndrome (RLS) is also a neurological disease characterised by sensory disorders and the urge to move predominantly legs and feet.

Approximately 1% of the population aged older than 60 years is suffering from PD; people under 40 years are rarely affected. Living in a rural environment, contact to pesticides, herbicides and industrial plants, and drinking of well water are thought to be risk factors. Men have a 1.5 times increased risk of developing this disease.

Approximately 10% of the population is experiencing symptoms of RLS. RLS can occur in children and adults, but the risk of developing RLS is increasing with age. Approximately 40% of the patients suffering from RLS had their first symptoms before they turned 20. Women are affected twice as often as men. Caucasian individuals are more often suffering from RLS than African Americans. RLS can be inherited, but can also occur due to iron deficiency in the context of pregnancy, renal failure and anaemia.

VI.2.2 Summary of treatment benefits

Pramipexol STADA contains the active substance pramipexole and belongs to a group of medicines known as dopamine agonists, which stimulate dopamine receptors in the brain. Stimulation of the dopamine receptors triggers nerve impulses in the brain that help to control body movements.

Pramipexol STADA is used to:

- treat the symptoms of primary Parkinson's disease (PD) in adults. It can be used alone or in combination with levodopa (another medicine for Parkinson's disease).
- treat the symptoms of moderate to severe primary Restless Legs Syndrome (RLS) in adults.

VI.2.3 Unknowns relating to treatment benefits

The elimination of pramipexole is dependent on renal function. The use of pramipexole has not been studied in haemodialysis patients, or in patients with severe renal impairment.

Pramipexol STADA is not recommended for use in children and adolescents below 18 years due to a lack of data on safety and efficacy for the treatment of restless-leg-sydnrme. There is no relevant use of pramipexole in the paediatric population in Parkinson's Disease.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	**What is known**	**Preventability**
Urge to behave in an unusual way (ICD and other abnormal behaviour)	Tell your doctor if you or your family/carer notices that you are developing urges or cravings to behave in ways that are unusual for you and you cannot resist the impulse, drive or temptation to carry out certain activities that could harm yourself or others. These are called impulse control disorders (ICD) and can include behaviours such as addictive gambling, excessive eating or spending, an abnormally high sex drive or preoccupation with an increase in sexual thoughts or feelings.	Always take this medicine as prescribed by your doctor and as indicated in the Package Leaflet. This will minimise the risk of developing adverse drug reactions.
Augmentation	As RLS patient, you may experience that symptoms start earlier than usual, be more intense and involve other limbs.	Tell your doctor if you have (had) or develop this medical condition or symptom. Always take this medicine as prescribed by your doctor and as indicated in the Package Leaflet. This will minimise the risk of developing adverse drug reactions.
Syndrome of inappropriate antidiuretic hormone secretion (SIADH)	Antidiuretic hormone acts on the kidney and controls the amount of water reabsorbed by the kidney. SIADH may lead to hyponatraemia. A precise frequency estimation is not possible, since this side effect was not observed in clinical studies. The frequency category is probably not greater than “uncommon”.	Always take this medicine as prescribed by your doctor and as indicated in the Package Leaflet. This will minimise the risk of developing adverse drug reactions.
Difficulties to breathe (Dyspnoea)	Dyspnoea may affect up to 1 in 100 people.	Always take this medicine as prescribed by your doctor and as indicated in the Package Leaflet. This will minimise the risk of developing adverse drug reactions.

Infection of the lungs (Pneumonia)	A precise frequency estimation is not possible, since this side effect was not observed in clinical studies. The frequency category is probably not greater than "uncommon" in patients treated for RLS. In patients treated for PD, pneumonia may affect up to 1 in 100 people.	Always take this medicine as prescribed by your doctor and as indicated in the Package Leaflet. This will minimise the risk of developing adverse drug reactions.
Heart problems which can cause shortness of breath or ankle swelling (Cardiac failure)	Recent studies suggest a potential risk of heart failure that needs further review of available data. A precise frequency estimation is not possible, since this side effect was not observed in clinical studies. The frequency category is probably not greater than "uncommon".	Always take this medicine as prescribed by your doctor and as indicated in the Package Leaflet. This will minimise the risk of developing adverse drug reactions.
Ocular structural degeneration (Retinal degeneration)	Visual impairment may affect up to 1 in 10 people treated for PD and up to 1 in 100 people treated for RLS.	Tell your doctor if you have (had) or develop vision impairment. You should have regular eye examinations during treatment with Pramipexol STADA.
Weight loss including decreased appetite (Decreased appetite/anorexia)	Weight loss may affect up to 1 in 10 people treated for PD and up to 1 in 100 people treated for RLS.	Always take this medicine as prescribed by your doctor and as indicated in the Package Leaflet. This will minimise the risk of developing adverse drug reactions.
Double vision (Diplopia)	Visual impairment may affect up to 1 in 10 people treated for PD and up to 1 in 100 people treated for RLS.	Tell your doctor if you have (had) or develop vision impairment. You should have regular eye examinations during treatment with Pramipexol STADA.
Vision disorder when you see shining rays or flashes of light (Photopsia)	Visual impairment may affect up to 1 in 10 people treated for PD and up to 1 in 100 people treated for RLS.	Tell your doctor if you have (had) or develop vision impairment. You should have regular eye examinations during treatment with Pramipexol STADA.

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Suicide-related behaviour	Patients treated with the medicinal product may be at an increased risk of developing this safety concern.
Delirium/mania	Patients treated with the medicinal product may be at an increased risk of developing this safety concern.
Bronchitis	Patients treated with the medicinal product may be at an increased risk of developing this safety concern.
Skin melanoma	Patients treated with the medicinal product may be at an increased risk of developing this safety concern.
Fibrotic events	Patients treated with the medicinal product may be at an increased risk of developing this safety concern.
Substance abuse/drug dependence	Patients treated with the medicinal product may be at an increased risk of developing this safety concern.
Hyperreflexia	Patients treated with the medicinal product may be at an increased risk of developing this safety concern.
Dystonia	Patients treated with the medicinal product may be at an increased risk of developing this safety concern.
Overdose	There is no clinical experience with massive overdose. The expected adverse reactions would be nausea, vomiting, hyperkinesia, hallucinations, agitation and hypotension.

Important missing information

None.

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.
The Summary of Product Characteristics and the Package leaflet for Pramipexole STADA can be found in the Pramipexole STADA's EPAR page.
This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

No post-authorisation studies have been imposed or are planned.

VI.2.7 Summary of changes to the Risk Management Plan over time

Not applicable.