Rasagilin Stada Arzneimittel AG 1 mg tablets

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PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

VI.2 Elements for a Public Summary

Rasagilin Stada Arzneimittel AG 1 mg tablets

VI.2.1 Overview of disease epidemiology

Parkinson's disease (PD) is a condition in which part of the brain becomes progressively damaged over many years. This manifests as progressive movement disorder, where main symptoms include slow movement, stiff and inflexible muscles and uncontrollable shaking. Depression, dementia (memory loss) and sleep disturbances may also occur.
PD affects 1% of the population over the age of 65 and 2% over the age of 80. However, one in 20 PD patients is diagnosed before reaching 40 years of age. Prevalence in Europe is estimated to be between 65.6 per 100,000 and 12,500 per 100,000 people and annual incidence is estimated to be between 5 per 100,000 and 346 per 100,000 people. PD may be slightly more common in males than in females.
Typical 1st line treatment includes levodopa, with other oral medication (such as rasagiline) if levodopa alone is insufficient to control the disease symptoms. In cases of severe disease complications where oral medicines prove insufficient, subcutaneous apomorphine may be started.

VI.2.2 Summary of treatment benefits

Rasagilin Stada Arzneimittel AG is used for the treatment of Parkinson's disease. It can be used together with or without levodopa (another medicine that is used to treat Parkinson's disease).

With Parkinson's disease, there is causes a loss of the cells that produce dopamine in the brain. Dopamine is a chemical in the brain involved in movement control. Rasagilin Stada Arzneimittel AG helps to increase and sustain levels of dopamine in the brain.

VI.2.3 Unknowns relating to treatment benefits

Rasagilin Stada Arzneimittel AG is not recommended for use in children and adolescents due to lack of data on safety and efficacy.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability

Head rush or dizzy spell (Orthostatic hypotension)	Orthostatic hypotension (head rush or dizzy spell), is a rapid blood pressure fall occurring when suddenly standing up or stretching. This adverse event occurred in approx. 3.9% of patients taking rasagiline compared to 0.8% in patients not taking the drug.	Please tell your doctor immediately if you suffer from headache, fever, shortness of breath and loss of consciousness. If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the package leaflet.
Serotonin syndrome	Serotonin syndrome is caused by an excessive level of chemical serotonin, leading to a spectrum of specific symptoms including confusion, agitation and headache. Symptoms may range from barely perceptible to fatal.	Please tell your doctor immediately if you suffer from any of the following: • Agitation or restlessness • Confusion • Rapid heart rate and high blood pressure • Dilated pupils • Loss of muscle coordination or twitching muscles • Muscle rigidity • Heavy sweating • Diarrhea • Headache • Shivering • Goose bumps
Impulse control disorders	Impulse control disorder is a psychiatric disorder which is characterized by impulsivity. Patients with an impulse control disorder can't resist the urge to do something harmful to themselves or others. Impulse control disorders include addictions to alcohol or drugs, eating disorders, compulsive gambling, paraphilias sexual fantasies and behaviors involving non-human objects, suffering, humiliation or children, compulsive hair pulling, stealing, fire setting and intermittent explosive attacks of rage.	Tell your doctor immediately if you suffer from changes in your impulsivity or your urge. If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the package leaflet.

Simultaneous use with antidepressants or other drugs (Concomitant use with antidepressants (SSRI, SnRI, tricyclic and tetracyclic antidepressants), CYP1A2 inhibitors or MAO inhibitors)	Serious adverse reactions (e.g. confusion, sleep, dyspnea) disorder have been reported with the concomitant use of SSRIs (e.g. citalopram, fluoxetine), SNRIs (e.g. tapentadol), tricyclic/ tetracyclic antidepressants (e.g. amitriptyline, desipramine) and MAO inhibitors (e.g. moclobemide, selegiline).	Please inform your doctor immediately about your co-medication and any changes in your co-medication. If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the package leaflet.

Important potential risks

Risk	**What is known (Including reason why it is considered a potential risk)**
High blood pressure (Hypertension)	In a dose escalation study in patients on chronic levodopa therapy treated with 10 mg/day of rasagiline, there were reports of cardiovascular undesirable reactions (including hypertension and postural hypotension) which resolved following treatment discontinuation.
Skin cancer (Malignant Melanoma)	During the clinical development program, the occurrence of cases of melanoma prompted the consideration of a possible association with rasagiline. The data collected suggests that Parkinson's disease, and not any medicinal products in particular, is associated with a higher risk of skin cancer (not exclusively melanoma). Any suspicious skin lesion should be evaluated by a specialist.
Simultaneous use with pethidin or other drugs (Concomitant use with pethidine or sympathomimetics)	Serious adverse reactions have been reported with the concomitant use of pethidine and MAO inhibitors including another selective MAO-B inhibitor. The concomitant administration of rasagiline and pethidine is contraindicated. At least 14 days must elapse between discontinuation of rasagiline and initiation of treatment with MAO inhibitors or pethidine.

Missing information

Risk	**What is known**

Pregnant and lactating women	For rasagiline no clinical data on exposed pregnancies is available. Animals studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development or postnatal development. Experimental data indicated that rasagiline inhibits prolactin secretion and thus, may inhibit lactation. It is not known whether rasagiline is excreted in human milk.

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.

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.