Solifenacin STADA 5 mg and 10 mg film-coated tablets

25.1.2017, Version V1.2

PUBLIC SUMMARY OF THE RISK MANAGEMENT PLAN

VI.2 Elements for a Public Summary

Solifenacin Stada 5 mg film-coated tablets
Solifenacin Stada 10 mg film-coated tablets

VI.2.1 Overview of disease epidemiology

Overactive bladder (OAB) syndrome is a condition where there is a frequent of feeling of needing to urinate. It is caused by sudden involuntary contraction (over activity) of the bladder detrusor muscles and is a common disorder that negatively affects the quality of life of patients. OAB can manifest itself through a combination of lower urinary tract symptoms, urinary frequency and urgency, which can occur with or without urinary incontinence (loss of bladder control). Incontinence is present in over half of patients with OAB.
The overall prevalence of overactive bladder symptoms in individuals aged 40 years or over has been estimated to be 16.6% across Europe. Urinary frequency was the most commonly reported symptom (85%), followed by urgency (54%) and urge incontinence (36%). The prevalence of overactive bladder symptoms increases with advancing age.

VI.2.2 Summary of treatment benefits

The active substance of Solifenacin Stada belongs to the group called anticholinergics. These medicines are used to reduce the activity of an overactive bladder. This enables you to wait longer before having to go to the bathroom and increases the amount of urine that can be held by your bladder.

Solifenacin Stada is used to treat the symptoms of a condition called overactive bladder. These symptoms include: having a strong, sudden urge to urinate without prior warning, having to urinate frequently or wetting yourself because you could not get to the bathroom in time.

VI.2.3 Unknowns relating to treatment benefits

The safety and efficacy of solifenacin in children and adolescents below 18 years have not yet been established.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	**What is known**	**Preventability**
Inability to empty the bladder (Urinary retention)	Inability to empty the bladder may affect up to 1 in 1,000 people.	Talk to your doctor or pharmacist if you are unable to pass water or to empty your bladder completely.
Allergic reactions (Hypersensitivity)	Allergic reactions (such as allergic rash) may affect up to 1 in 10,000 people.	If you experience an allergic attack, or a severe skin reaction (e.g. blistering and peeling of the skin), you must

		inform your doctor or pharmacist immediately. Symptoms of an allergic reaction can vary, but may include swelling under the skin, breathing difficulty, itching, rash, and hives.
Cardiac rhythm disorders (Cardiac rhythm disorders)	In case of overdosing, risk of abnormal ECG findings exists. This risk may be higher in patients with low potassium levels, slow heart rate, those concurrently taking medicinal products known to cause ECG abnormalities and in patients with relevant pre-existing cardiac diseases.	Immediately tell your doctor of pharmacist if you notice a change in heart rate (palpitations, irregular or fast heartbeat).
Eye diseases which results in damage to the optic nerve and vision loss (Glaucoma)	Glaucoma is a group of eye conditions that damage the optic nerve, which is vital to good vision. This damage is often caused by an abnormally high pressure in the eye.	DO NOT take Solifenacin Stada if you suffer from increased pressure in the eyes, with gradual loss of eye sight (glaucoma) Contact your doctor immediately if you experience any of the following symptoms: • Severe headache • Eye pain • Nausea and vomiting • Blurred vision • Patchy blind spots in your side or central vision, frequently in both eyes
Bowel obstruction (Ileus)	Bowel obstruction may occur with the use of Solifenacin Stada. The frequency is unknown.	Contact your doctor immediately if you experience any of the following symptoms: • Mild abdominal pain • Bloating • Constipation

Important potential risks

Risk	**What is known (Including reason why it is considered a potential risk)**
Use of solifenacin in infants and children whether exposed to solifenacin directly or exposed via breast-feeding	No data on the excretion of solifenacin in human milk are available. In mice, solifenacin and/or its metabolites was excreted in milk, and caused a dose dependent failure to thrive in neonatal mice. The use of solifenacin should therefore be avoided during breastfeeding.

Missing information

Risk	What is known
Use in pregnancy	No clinical data are available from women who became pregnant while taking solifenacin. Animal studies do not indicate direct harmful effects. The potential risk for humans is unknown. Caution should be exercised when prescribing to pregnant women.

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