sRMP

Solifenacin

DK/H/2188/001-002/E/001/MR

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Solifenacin Teva 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.

In Europe it is estimated that 16.6 % of the people above 40 years of age are affected by the disease.

VI.2.2 Summary of treatment benefits

The active substance of Solifenacin Teva belongs to the group of 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.

VI.2.3 Unknowns relating to treatment benefits

Not applicable.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	**What is known**	**Preventability**
Liver disease	Solifenacin is extensively metabolised by the liver.	• Do not take solifenacin if you have moderate liver disease AND at the same time are being treated with medicines that may decrease the removal of Solifenacin from the body (for example, ketoconazole). • Inform your doctor if you have moderate liver disease
Kidney disease	Patients with severe kidney disease should be treated with caution	• Do not take solifenacin if you if you are undergoing kidney dialysis. • Do not take solifenacin if you suffer from severe kidney disease AND at the same time are being treated with medicines that may decrease the removal of solifenacin from the body (for example, ketoconazole). • Inform your doctor if you suffer from severe kidney disease.
Lodging of a large amount of hardened stool in the large intestine (faecal impaction), obstruction of the digestive system	Solifenacin might commonly slow down your digestive system	• Do not take solifenacin if you have a severe stomach or bowel condition • Inform your doctor if you have some obstruction of the digestive system. • Inform your doctor if you are at risk of your digestive system slowing down.
Build up of urine in the bladder due to inability to empty the bladder	There is a rare risk of accumulation of urine in the	• Do not take Solifenacin if you have an inability to pass water or to empty your bladder completely.

Risk	What is known	Preventability
(urinary retention)	bladder.	• Inform your doctor if you have trouble emptying your bladder (i.e bladder obstruction) or have difficulty in passing urine (e.g. a thin urine flow).
Reflux disease (gastro-oesophageal reflux)	Uncommonly solifenacin might cause reflux disease	• Inform your doctor if you have a stomach tear (hiatus hernia) or heartburn. • It is especially important to inform your doctor if you are taking medicines such as bisphosphonates, that can cause or exacerbate inflammation of the gullet (oesophagitis)

Important potential risks

Risk	What is known (Including reason why it is considered a potential risk)
Changes in the electrical activity of the heart	Changes in the electrical activity of the heart have been reported in association with solifenacin use in worldwide postmarketing experience. Because these spontaneously reported events are from the worldwide postmarketing experience, the frequency of events and the role of solifenacin in their causation cannot be reliably determined.
Erythema multiforma	Very rarely solifenacin might cause allergic rash.
Skin allergy that results in the swelling that occurs in the tissue just below the surface of the skin (angioedema)	Angioedema (skin allergy that results in the swelling that occurs in the tissue just below the surface of the skin) with airway obstruction (difficulty in breathing) has been reported in some patients on solifenacin. If angioedema occurs, you should immediately discontinue taking solifenacin and consult your doctor.
Confusional state	Very rarely solifenacin might cause confusion.
Sleepiness (somnolence)	Uncommonly solifenacin might cause sleepiness. The ability to drive and use machines may be negatively affected. If you suffer from sleepiness, do not drive or operate machinery.

Risk	What is known (Including reason why it is considered a potential risk)
Abdominal pain	Commonly solifenacin might cause abdominal pain.
Urinary tract infection	Uncommonly solifenacin might cause urinary tract infection.

Important missing information

Risk	What is known
Use in children	Safety and effectiveness in children have not yet been established. Therefore, solifenacin should not be used in children.

VI.2.5 Summary of risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) 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

Not applicable.

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

Major changes to the Risk Management Plan over time

Version	Date	Safety Concerns	Comment
1.0	At time of initial marketing authorisation application submission: 25-Jul-2012 (Release date)	**Identified risks:** • None **Potential risks:** • QT Prolongation **Missing information:** • Use in Children	Preapproval
1.1	01-May-2013	**Identified risks:** • Hepatic impairment • Renal impairment • Faecal impaction, constipation and colonic obstruction • Urinary retention • Gastro-oesophageal reflux **Potential risks:** • QT Prolongation • Erythema multiforma • Angioedema **Missing information:**	Preapproval

Version	Date	Safety Concerns	Comment
		• Use in Children	
1.2	28-Oct-2013	**Identified risks:** • Hepatic impairment • Renal impairment • Faecal impaction, constipation and colonic obstruction • Urinary retention • Gastro-oesophageal reflux **Potential risks:** • QT Prolongation • Erythema multiforma • Angioedema • Confusional state • Somnolence • Abdominal pain • Urinary tract infection **Missing information:** • Use in Children	