

PUBLIC SUMMARY OF RISK MANAGEMENT PLAN

DATE: 07-03-2016, VERSION 1.1

VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Solifenacin Orion is used to treat 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 because the patient could not get to the toilet in time.

Overactive bladder is a problem with bladder-storage function that causes a sudden urge to urinate. The urge may be difficult to stop, and overactive bladder may lead to the involuntary loss of urine (incontinence). Overactive bladder occurs because the muscles of the bladder start to contract involuntarily even when the volume of urine in the bladder is low. This involuntary contraction creates the urgent need to urinate. Several conditions may contribute to signs and symptoms of overactive bladder, but often the specific cause of an overactive bladder isn't known.

The prevalence of over active bladder in Europe has been estimated to be 15.6 and 17.4% for men and women respectively, with an overall prevalence of 16.6%.

Male gender, advanced age and obesity, are some of the common risk factors for over active bladder.

VI.2.2 Summary of treatment benefits

Solifenacin helps to treat symptoms of an overactive bladder such as urinary incontinence, urinary urgency or frequency. It belongs to a class of medicines called anticholinergics. These medicines are used to reduce the activity of an overactive bladder. Solifenacin works by relaxing and preventing spasms of the bladder muscle. This enables patient to wait longer before having to go to the toilet and increases the amount of urine that can be held by the bladder.

VI.2.3 Unknowns relating to treatment benefits

The safety and efficacy of Solifenacin Orion in children and adolescents below 18 years have not yet been established. Therefore, Solifenacin Orion should not be used in children and adolescents.

Safety and efficacy have not yet been established in patients with a neurogenic cause for overactivity of the bladder wall muscles.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
Buildup of urine in the bladder due to inability to empty the bladder (Urinary retention)	<p>Rare side effects associated with solifenacin therapy include buildup of urine in the bladder due to inability to empty the bladder. This can also happen in case of overdose.</p> <p>Risk of accumulation of urine in the bladder (urinary retention) is much higher in patients who have trouble emptying the bladder (= bladder obstruction) or have difficulty in passing urine (e.g. a thin urine flow).</p>	<p>Solifenacin must not be used in patients who have an inability to pass water or to empty the bladder completely.</p> <p>Solifenacin should be used with caution in patients with clinically significant bladder outflow obstruction.</p>
Change in the electrical activity of the heart (ECG) (QT prolongation) and serious heart rhythm disturbance (Torsade de Pointes)	<p>QT prolongation and Torsade de Pointes have been observed in patients with risk factors in association with solifenacin therapy. Known risk factors for QT-prolongation are e.g. too low potassium levels in blood, slow heart beat and concurrent administration of medicinal products known to prolong QT-interval and relevant pre-existing heart diseases.</p> <p>In case of overdosing, specific attention should be paid to patients with known risk for QT-prolongation.</p>	<p>Doctor should be informed of patient's medical history and possible concomitant medications before onset of solifenacin therapy. Caution should be administered if the patient has any of the risk factors for QT prolongation.</p>
Increased pressure in the eyes, with gradual loss of eye sight (glaucoma)	<p>Increased pressure in the eyes has been reported in association with solifenacin therapy.</p>	<p>Solifenacin must not be used if the patient has suffers from increased pressure in the eyes, with gradual loss of eye sight.</p>

Risk	What is known	Preventability
Obstruction of the digestive system (Ileus)	Intestinal obstruction, constipation and lodging of a large amount of hardened stool in the large intestine (faecal impaction) has been reported in association with solifenacin therapy.	<p>Patients with severe stomach or bowel condition (including toxic megacolon, a complication associated with ulcerative colitis) must not take solifenacin.</p> <p>Caution should be administered in patients with some obstruction of the digestive system or in patients who are at risk of their digestive system (stomach and bowel movements) slowing down.</p>
Severe hypersensitivity reactions (angioedema, anaphylactic reaction)	<p>Severe hypersensitivity reactions have been reported in association with solifenacin therapy.</p> <p>Angioedema is the swelling of the deeper layers of the skin, caused by a build-up of fluid. The symptoms of angioedema can affect any part of the body, but swelling usually affects the eyes, lips, genitals, hands and feet.</p> <p>Anaphylactic reaction is a serious allergic reaction. It can begin very quickly, and symptoms may be life-threatening.</p> <p>Symptoms can be e.g. hives, itchiness, or redness all over the body and swelling of the lips, tongue, or back of the throat, trouble breathing, severe gastrointestinal symptoms such as abdominal cramps, diarrhea, or vomiting, dizziness or fainting (signs of a drop in blood pressure).</p>	Solifenacin must not be used in patients who are allergic to solifenacin or any of the other ingredients of this medicine.

Important potential risks

None identified.

Missing information

Risk	What is known
Use of solifenacin in infants and children either 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 adverse effects in neonate. The use of Solifenacin Orion should therefore be avoided during breastfeeding.
Use in pregnancy	No clinical data are available from women who became pregnant while taking solifenacin. Animal studies do not indicate direct harmful effects on fertility, fetal development or birth. However, the potential risk for humans is unknown. Therefore caution should be administered.

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. The Summary of Product Characteristics and the Package leaflet for this medicinal product can be found in the national authority's web page.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan (if applicable)

Not applicable.

VI.2.7 Summary of changes to the risk management plan over time

Not applicable.