VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

OAB syndrome:

OAB is a common disorder that negatively affects the quality of life of patients and carries a large socioeconomic burden OAB is a condition caused by sudden involuntary contraction (over activity) of the bladder detrusor muscles. On the basis of a population-based survey of 16, 776 men and women aged 40 years and older selected from 6 countries France, Germany, Italy, Spain, Sweden and the United Kingdom, the prevalence of OAB in Europe has been estimated to be 15.6 and 17.4% for men and women respectively, with an overall prevalence of 16.6%. In the National Overactive Bladder Evaluation survey in which 11740 Americans agreed to participate, overall prevalence of OAB was 16.9% in women and 16.0% in men. Male gender, advanced age and obesity, are some of the common risk factors for OAB.

VI.2.2 Summary of treatment benefits

Accord has not conducted any studies for solifenacin on expected benefit considering its similarity to the currently marketed product (Vesicare5 mg and 10 mg film-coated tablets, Astellas Pharma Ltd) used for the treatment of the symptoms of overactive bladder syndrome, where the patient may find that he is unable to control urination that may need to rush to the toilet with no advance warning and/or go to the toilet frequently.

Treatment with solifenacinin doses of 5 mg and 10 mg daily was studied in several clinical trials in men and women with OAB. Both the 5 mg and 10 mg doses of solifenacin produced significant improvements. Efficacy was observed within one week of starting treatment and stabilised over a period of 12 weeks. After 12 weeks of treatment, approximately 50% of patients suffering from incontinence before treatment were free of incontinence episodes, and in addition 35% of patients achieved a micturition frequency of less than 8 micturitions per day. A long-term study demonstrated that efficacy was maintained for at least 12 months. Treatment of the symptoms of OAB also results in a benefit on a number of quality of life measures, such as general health

perception, incontinence impact, role limitations, physical limitations, social limitations, emotions, symptom severity, severity measures and sleep/energy.

VI.2.3 Unknowns relating to treatment benefits

Not known

VI.2.4 Summary of safety concerns

Important identified risks

Risk	**What is known**	**Preventability**
Abnormal Electrocardiogram finding (QT interval prolongation)	QT prolongation and Torsade de Pointes have been observed in patients with risk factors, such as pre-existing long QT syndrome, low heart rate, low potassium level and concurrent consumption of medicinal products known to cause QT prolongation.	Yes Patient should inform treating doctor their complete details of medical history and drugs ongoing. Patient should inform doctor or pharmacist immediately if experience symptoms like dizziness, recurrent episodes of feeling of heart beats, loss of consciousness, shortness in breath, chest pain.

Important potential risks

Risk	**What is known**

Skin allergy that results in the swelling that occurs in the tissue just below the surface of the skin with difficulty in breathing (Angioedema with airwayobstruction)	Skin allergy that results in the swelling that occurs in the tissue just below the surface of the skin with difficulty in breathing has been reported in some patients on solifenacin succinate. If this occurstreatment should be discontinued immediately and appropriate therapy and/or measures should be taken.
Build up of urine in the bladder due to inability to empty the bladder (Urinary retention in patients with significant bladder outlet obstruction)	Rare side effects include build up of urine in the bladder due to inability to empty the bladder. Patint is advised not to take Solifenacin if you have inability to pass water or to empty your bladder completely. Symptoms of overdose of Solifenacin include accumulation of urine in the bladder (urinary retention).
Worsening of effects in patients with gastrointestinal disorders	Common side effects of Solifenacin include constipation, nausea, and indigestion with symptoms such as abdominal fullness, abdominal pain, burping, and nausea, and heartburn (dyspepsia), stomach discomfort. Patint is advised not to take Solifenacin if you havesevere stomach or bowel condition (including toxic megacolon, a complication associated with ulcerative colitis).Talk to your doctor or pharmacist before taking Solifenacin if you are at risk of your digestive system slowing down (stomach and bowel movements).Common side effects of Solifenacin include constipation, nausea, indigestion with symptoms such as

	abdominal fullness, abdominal pain, burping, nausea, and heartburn (dyspepsia), stomach discomfort.

Missing information

Risk	**What is known**
Limited information on the use in pediatric population	Solifenacin is not to be used in children or adolescents under 18 years.
Limited information on the use in pregnant women	One should not use solifenacin if she is pregnant unless doctor thinks it is necessary.
Limited information on the effect on fertility of humans	No fertility data are available. In case of pregnancy or a plan to have a baby, prior advice from doctor or pharmacist is necessary.

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 risksand recommendations for minimising them. An abbreviated version of this in lay language isprovided in the form of the package leaflet (PL). The measures in these documents are known asroutine risk minimisation measures.

This medicine has no additional risk minimisation measures.

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

No studies planned.

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

Version	Date	Safetyconcerns	Comment
2.0	31 January 2014	Followingriskswereadded: *Important identified risk:* QT interval prolongation *Important potential risk:* Urinary retention in patients with significant bladder outlet obstruction worsening of effects in patients with gastrointestinal disorders	Table VI.2.4 explained in layman language. RMP template updated as per "Guidance on format of the risk management plan (RMP) in the EU for Generics". EMA/465933/2013 Rev.1 Dated: 25 July 2013.