## VI.2 Elements for a public summary

### VI.2.1 Overview of disease epidemiology

**Overactive bladder syndrome:**

Overactive bladder (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 (overactivity) 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, by telephone or direct interview, 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%. [(2) (3)]. In the NOBLE survey in which 11740 Americans agreed to participate, overall prevalence of OAB was 16.9% in women and 16.0% in men. [(4)]

### VI.2.2 Summary of treatment benefits

Accord has not conducted any studies for tolterodine on expected benefit considering its similarity to the currently marketed product (Detrusitol 1 mg and 2 mg tablets, Pfizer 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.

### VI.2.3 Unknowns relating to treatment benefits

Efficacy in the paediatric population has not been demonstrated. Two paediatric phase 3 randomised, placebo-controlled, double blind 12 week studies were conducted by the originator product using tolterodine extended release capsules. A total of 710 paediatric patients (486 on tolterodine and 224 on placebo) aged 5-10 years with urinary frequency and urge urinary incontinence were studied. No significant difference between the two groups was observed in either study with regard to change from baseline in total number of incontinence episodes/week.

### VI.2.4 Summary of safety concerns

**Important identified risks**

| Risk | What is known | Preventability |
|---|---|---|
| Abnormal heart tracing (ECG) (QT interval prolongation) | Possible side effects:<br>Common: Palpitations,<br>Uncommon: Increased heart rate, Irregular heartbeat, Heart failure<br>In case of tolterodine overdose, increase in QT interval reported [5] | Yes<br>Take special care if you have a heart condition such as: an abnormal heart tracing (ECG); a slow heart rate (bradycardia); relevant pre-existing cardiac diseases (cardiomyopathy (weak heart muscle), myocardial ischaemia (reduced blood flow to the heart), arrhythmia (irregular heartbeat) and heart failure)<br>If you are taking any medicine for the treatment of an irregular heartbeat (arrhythmia) [5] |

**Important potential risks**

| Risk | What is known |
|---|---|
| Urinary retention in patients with significant bladder outlet obstruction | Do not take tolterodine if you are unable to pass urine from the bladder (urinary retention).<br>Inform doctor if you have difficulties in passing urine and/or a poor stream of urine [5] |

| Risk | What is known |
|---|---|
| | Possible side effects:<br>Common - inability to empty the bladder, painful or difficult urination [5] |
| Potential worsening of effects in patients with gastrointestinal disorders | Do not take tolterodine if you suffer from severe ulcerative colitis (ulceration and inflammation of the colon) or a toxic megacolon (acute dilatation of the colon). [5]<br>Inform doctor if have a gastro-intestinal disease that affects the passage and/or digestion of food or have ever experience decreased bowel movements or suffer from severe constipation (decreased gastro-intestinal motility). [5]<br>Possible side effects:<br>Very common – Dry mouth; Common - Bad digestion (dyspepsia), vomiting, Diarrhoea, Excessive amounts of air or gases in the stomach or the intestine, Constipation, Abdominal pain [5] |

**Missing information**

| Risk | What is known |
|---|---|
| Limited information on the use in Paediatric population | Tolterodine Film-coated Tablets is not recommended for children. [5] |
| Limited information on the use in pregnant and lactating | Patients should not use tolterodine when pregnant. Patients are advised to contact doctor immediately if they are pregnant, think they are pregnant or are planning to become pregnant. [5] |

| | |
|---|---|
| mothers | Lactation: It is not known if tolterodine is excreted in the mother's breast milk. Breast feeding is not recommended during administration of tolterodine. (5) |

### 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 tolterodine can be found in the tolterodine's EPAR.

This medicine has no additional risk minimisation measures.

### VI.2.6 Planned post authorisation development plan

No studies planned.

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

| Version | Date | Safety Concern | Comment |
|---|---|---|---|
| 2.0 | 12-November-2013 | Following safety concerns are included:<br>**Important identified risk**:<br>QT interval prolongation<br>**Important potential risk:** | - |

| Version | Date | Safety Concern | Comment |
|---|---|---|---|
| | | Urinary retention in patients with significant bladder outlet obstruction<br><br>Potential worsening of effects in patients with gastrointestinal disorders | |