VI.2 Elements for a public summary

VI.2.1 Overview of disease epidemiology

Preterm birth, defined as childbirth occurring at less than 37 completed weeks or 259 days of gestation. Children who are born prematurely have higher rates of brain damage leading to problems of movement, muscle tone, and/or posture (cerebral palsy), sensory deficits, learning disabilities and respiratory illnesses compared with children born at term. Of all early neonatal deaths (deaths within the first 7 days of life) that are not related to congenital malformations, 28% are due to preterm birth. Preterm birth rates have been reported to range from 5% to 7% of live births in some developed countries, but are estimated to be substantially higher in developing countries. It is, however, unclear whether preterm birth results from the interaction of several pathways or the independent effect of each pathway. Causal factors linked to preterm birth include medical conditions of the mother or fetes, genetic influences, environmental exposure, infertility treatments, behavioural and socioeconomic factors and iatrogenic prematurity.

VI.2.2 Summary of treatment benefits

Atosiban is used to delay imminent pre-term birth in pregnant adult women with regular uterine contractions of at least 30 seconds duration at a rate of ≥ 4 per 30 minutes, a cervical dilation of 1 to 3 cm (0-3 for nulliparas) and effacement of ≥ 50%, a gestational age from 24 until 33 completed weeks and a normal foetal heart rate.

A study was conducted in 742 women who were diagnosed with pre-term labour at 23–33 weeks of gestation and were received either atosiban or other drug (β-agonist). Result has shown that 59.6% (n=201) and 47.7% (n=163) of atosiban- and β -agonist-treated women, respectively, were undelivered and did not require alternative labour reduction (tocolysis) within 7 days of starting treatment..

VI.2.3 Unknowns relating to treatment benefits

Information on interaction of atosiban with antihypertensive agent except labetalol and antibiotics are not available and the efficacy of atosiban in women less than 18 years of age and

in patients with impaired hepatic and renal functions has not been studied. There is only limited clinical experience in the use of atosiban in multiple pregnancies or the gestational age group between 24 and 27 weeks, because of the small number of patients treated. The benefit of atosiban in these subgroups is therefore uncertain.

VI.2.4 Summary of safety concerns

Important identified risk

Risk	**What is known**	**Preventability**
Short of breath (dyspnoea) and accumulation of fluid in the lung (pulmonary oedema)	Patient may experience shortness of breath or lung oedema (accumulation of fluid in the lungs), particularly if she is pregnant with more than one baby and/or are given medicines that can delay the birth of baby, such as medicines used for high blood pressure	Patient should inform their doctor or pharmacist or nurse before taking atosiban if they are pregnant with more than one baby and/or are given medicine that can delay birth of baby such as medicines used for high blood pressure.

Important potential risks

Risk	**What is known**
Off-label use	None
Urinary tract infection	None

Missing information

Risk	**What is known**

Risk	What is known
Interaction with other drugs used to delay the birth of baby (tocolytics), antibiotics and medicine used for high blood pressure (anti-hypertensive agents)	Patient may experience shortness of breath or lung oedema (accumulation of fluid in the lungs), particularly if she is given medicines that can delay the birth of baby, such as medicines used for high blood pressure. Interaction studies have been performed with labetalol and betamethasone in healthy, femalevolunteers.
Multiple pregnancies	Limited information available on use of Atosiban in pregnant women with more than one baby. This along with drugs used to delay the birth of baby may increase the risk of the accumulation of fluid in the lung (pulmonary oedema).

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 minimizing 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 studies planned

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

Version	Date	Safety Concern	Comment
2.0	07 December 2017	No change in safety concerns	RMP has been updated as per revised SPC and PIL.