VI.2 Elements for a Public Summary

VI.2.1 Overview of disease epidemiology

Labour induction can be used before child birth in cases of delayed start of child birth, premature rupture of membranes or pregnancy toxaemia (preeclampsia).
Labour induction can be used after child birth in cases during caesarean section after delivery of the child and prevention and treatment of uterus bleeding (uterine haemorrhage) and loss of tone in the uterus musculature (atony).
It's fairly common for labour to be induced. Every year, one in five labours are induced in the UK.[i]

VI.2.2 Summary of treatment benefits

Oxytocin is used to start or help contractions during childbirth (labour), to prevent and control bleeding after delivery of your baby and during a caesarean section.

Oxytocin stimulates the smooth muscle of the uterus, more powerfully towards the end of pregnancy, during labour, and immediately after child birth.
In small doses as intravenous infusion oxytocin elicits rhythmic contractions in upper segment of uterus, similar in frequency, force and duration to those observed during labour.
In addition to the effects on uterus, oxytocin pulls together cells of the mammary gland, which induces lactation and thereby makes the breastfeeding process easier.

VI.2.3 Unknowns relating to treatment benefits

None.

VI.2.4 Summary of safety concerns

Important identified risks

Risk	What is known	Preventability
• **Excessive doses resulting in uterus (uterine)oversti-mulation**	Administration of oxytocin at excessive doses results in uterus (uterine) overstimulation which may cause that fetus does not receive adequate amounts of oxygen (foetal distress,	Careful monitoring of foetal heart rate and uterine motility (frequency, strength, and duration of contractions) is essential, so that the dosage may be adjusted

Risk	What is known	Preventability
	asphyxia) and death, or may lead to increased tension of the muscles (hypertonicity), sustained muscle contraction (tetanic contractions) or rupture of the uterus.	to individual response. The frequency, strength, and duration of contractions as well as the foetal heart rate must be carefully monitored throughout the infusion. Once an adequate level of uterine activity is attained, the infusion rate can often be reduced. In the event of uterine hyperactivity and/or foetal distress, the infusion must be discontinued immediately.
• **Allergic (Hypersensitivity) reaction**	Allergic reactions to the active substance or to any of the excipients may occur. Immediate serious allergic reaction, such as anaphylactic reactions associated with shortness of breath (dyspnea), low blood pressure (hypotension) or shock is a possible adverse reaction, which occurs rarely.	There is no specific measure to prevent the occurrence. The risk can be reduced by not allowing the product to be used in patients with known allergy (hypersensitivity) to the active substance or to any of the excipients.
• **Condition in which small blood clots develop throughout the bloodstream, blocking small blood vessels (Disseminated intravascular coagulation, DIC)**	In rare circumstances, the induction of labour using agents like oxytocin increases the risk of small blood clots developing throughout the bloodstream, blocking small blood vessels (disseminated intravascular coagulation, DIC). This risk is increased in particular if the woman has additional risk factors for DIC such as being 35 years of age or more, complications during pregnancy and gestational age more than 40 weeks.	There is no specific measure to prevent the occurrence. The risk can be reduced by not allowing the product to be used in women being 35 years of age or more, women with complications during pregnancy and women with gestational age more than 40 weeks. In these women, oxytocin or any other alternative medicine should be used with caution, and the practitioner should be alerted by signs of DIC.
• **Too much water in the body associated with too low sodium levels (Water intoxication associated with hyponatraemia)**	Too much water in the body associated with too low sodium levels for mother and fetus has been reported in cases where high doses of oxytocin together with large amounts of electrolyte-free fluid have been administrated over a prolonged period of time.	To avoid these rare complications, the following precautions must be observed whenever high doses of oxytocin are administrated over a long time: an electrolyte-containing diluent must be used (not dextrose); the volume of infused fluid should be kept low (by infusing oxytocin at a higher concentration than recommended for the induction or enhancement of labour at term); fluid intake by mouth must be restricted; a fluid balance chart should be kept, and serum electrolytes should be measured when electrolyte imbalance is suspected.

Risk	What is known	Preventability
		In cases of water intoxication it is essential to restrict fluid intake, promote urination (diuresis), correct electrolyte imbalance, and control convulsions that may eventually occur, e.g. using medicine (diazepam) carefully.
• **Excess of fluid in the body leading to fluid accumulation in the lungs (Fluid overload leading to acute pulmonary oedema)**	A combined effect of oxytocin and the intravenous fluid administration may cause excess of fluid in the body (fluid overload) leading to fluid accumulation in the lungs (acute pulmonary oedema) without low sodium levels.	To avoid these rare complications, the following precautions must be observed whenever high doses of oxytocin are administrated over a long time: an electrolyte-containing diluent must be used (not dextrose); the volume of infused fluid should be kept low (by infusing oxytocin at a higher concentration than recommended for the induction or enhancement of labour at term); fluid intake by mouth must be restricted; a fluid balance chart should be kept, and serum electrolytes should be measured when electrolyte imbalance is suspected.
• **Heart condition with prolonged heartbeat (Prolonged QT interval)**	Oxytocin may increase the risk for developing heart condition with prolonged heartbeat (Prolonged QT interval). Rapid injection via the veins of a relatively large volume (intravenous bolus injection) of oxytocin at doses more than a few grams may also result in prolonged QT interval.	Oxytocin BBS should be given with caution to patients with known “prolonged QT syndrome” or related symptoms and to patients taking drugs that are known to prolong the QT interval.
• **Adverse reactions following injection via the veins of a relatively large volume (i.v. bolus injection)**	Oxytocin BBS must only be administrated as an infusion and never by injection via the veins of a relatively large volume, as it may cause an acute short-lasting low blood pressure (hypotension) accompanied with flushing and reflex tachycardia. These rapid changes in dynamics of blood flow may result in too low oxygen supply to the heart (myocardial ischaemia), particularly in patients with pre-existing cardiovascular disease. Rapid intravenous injection of a relatively large volume of oxytocin at doses more than a few grams may also result in a heart condition with	The occurrence can be prevented by not using the product by injection of a relatively large volume, via the veins (i.v. bolus injection).

Risk	What is known	Preventability
	prolonged heart beat (prolonged QT interval).	
• **Changes in physical effects of blood flow (haemodynamic) in patients with pre-existing cardiovascular disease**	Oxytocin BBS should be used with caution in patients who have a pre-disposition of too low oxygen supply to the heart (myocardial ischaemia) due to pre-existing cardiovascular disease to avoid significant changes in blood pressure and heart rate in these patients.	Oxytocin BBS should be given with caution to patients with pre-existing cardiovascular disease.

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 Oxytocin BBS can be found in the homepage of the National Health Authority.

This medicine has no additional risk minimisation measures.

VI.2.6 Planned post authorisation development plan

None.

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

Not applicable as this is the initial risk management plan.