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*This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

# Revision of Precautions

## Oxytocin

June 25, 2020

### **Therapeutic category**

Pituitary hormone preparations

### **Non-proprietary name**

Oxytocin

### **Safety measure**

Precautions should be revised in the package insert.

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
<p><b>Warnings</b></p> <p>In using this drug for labour induction or treatment of weak labour:            Patients should be fully informed of the necessity of labour induction and treatment of weak labour with this drug along with the risks associated, and <u>this drug</u> should be administered after their consent is obtained.</p> <p><u>Foetal heart rates and maternal uterine contraction status should be closely monitored</u> with an electronic foetal monitor.</p>	<p><b>Warnings</b></p> <p>In using this drug for labour induction or treatment of weak labour:  <u>This drug should be used in a hospital setting with facilities to enable continuous monitoring of maternal and foetal conditions with an electronic foetal monitor and under the supervision of a physician who has sufficient knowledge and experience in the management of labour and delivery as well as of the safety profile of this drug.</u> Patients should be fully informed of the necessity of labour induction and treatment of weak labour with this drug along with the risks associated <u>prior to administration,</u> and administration of this drug should be <u>initiated</u> after their consent is obtained.</p> <p><u>Monitoring with an electronic foetal monitor should be continued throughout the administration of this drug except for temporary removal of the monitor for patients to walk to the bathroom or when otherwise permitted by their physicians as necessary, and appropriate measures should be taken if any abnormalities are observed.</u></p>
<p><b>Important Precautions</b></p> <p>With or without medication use, life-threatening emergencies (uterine rupture, amniotic fluid embolus, intra-cerebral</p>	<p><b>Important Precautions</b></p> <p>With or without medication use, life-threatening emergencies (uterine rupture, amniotic fluid embolus, intra-cerebral</p>

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<p>haemorrhage, subarachnoid haemorrhage, premature separation of placenta, eclampsia, intrapartum massive bleeding, etc.) may arise in mothers during labour. When labour is induced or weak labour is treated with this drug, patients should be carefully observed by <u>labour monitoring</u> with an electronic foetal monitor as well as regularly checking vital signs, and appropriate measures should be taken if any abnormalities are observed.</p>	<p>haemorrhage, subarachnoid haemorrhage, premature separation of placenta, eclampsia, intrapartum massive bleeding, etc.) may arise in mothers during labour. When labour is induced or weak labour is treated with this drug, patients should be carefully observed <u>by continuous monitoring</u> with an electronic foetal monitor <u>intended for close monitoring of maternal and foetal conditions</u> as well as regularly checking vital signs, and appropriate measures should be taken if any abnormalities are observed. <u>Continuous monitoring with an electronic foetal monitor may be interrupted temporarily for patients to walk to the bathroom or when otherwise permitted by their physicians as necessary but such interruption of monitoring should not be prolonged.</u></p>
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Revision in line with the Instructions for Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0608-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 8, 2017 (New instructions): Revised language is underlined.

Current	Revision
<p>1. WARNINGS</p> <p>&lt;Labour induction, weak labour&gt;</p> <p>Patients should be fully informed of the necessity of labour induction and treatment of weak labour with this drug along with the risks associated, and <u>this drug</u> should be administered after their consent is obtained.</p>	<p>1. WARNINGS</p> <p>&lt;Labour induction, weak labour&gt;</p> <p><u>This drug should be used in a hospital setting with facilities to enable continuous monitoring of maternal and foetal conditions with an electronic foetal monitor and under the supervision of a physician who has sufficient knowledge and experience in the management of labour and delivery as well as of the safety profile of this drug.</u> Patients should be fully informed of the necessity of labour induction and treatment of weak labour with this drug along</p>

<p><u>Foetal heart rates and maternal uterine contractions status should be closely monitored</u> with an electronic foetal monitor.</p>	<p>with the risks associated <u>prior to administration</u>, and administration of this drug should be <u>initiated</u> after their consent is obtained.</p> <p><u>Monitoring with an electronic foetal monitor should be continued throughout the administration of this drug except for temporary removal of the monitor for patients to walk to the bathroom or when otherwise permitted by their physicians as necessary, and appropriate measures should be taken if any abnormalities are observed.</u></p>
<p><b>8. IMPORTANT PRECAUTIONS</b></p> <p>With or without medication use, life-threatening emergencies (uterine rupture, amniotic fluid embolus, intra-cerebral haemorrhage, subarachnoid haemorrhage, premature separation of placenta, eclampsia, intrapartum massive bleeding, etc.) may arise in mothers during labour. When labour is induced or weak labour is treated with this drug, patients should be carefully observed by <u>labour monitoring</u> with an electronic foetal monitor as well as regularly checking vital signs and appropriate measures should be taken if any abnormalities are observed.</p>	<p><b>8. IMPORTANT PRECAUTIONS</b></p> <p>With or without medication use, life-threatening emergencies (uterine rupture, amniotic fluid embolus, intra-cerebral haemorrhage, subarachnoid haemorrhage, premature separation of placenta, eclampsia, intrapartum massive bleeding, etc.) may arise in mothers during labour. When labour is induced or weak labour is treated with this drug, patients should be carefully observed <u>by continuous monitoring</u> with an electronic foetal monitor <u>intended for close monitoring of maternal and foetal conditions</u> as well as regularly checking vital signs and appropriate measures should be taken if any abnormalities are observed. <u>Continuous monitoring with an electronic foetal monitor may be interrupted temporarily for patients to walk to the bathroom or when otherwise permitted by their physicians as necessary but such interruption of monitoring should not be prolonged.</u></p>

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