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Revision of Precautions

Dinoprostone (oral dosage form)

June 25, 2020

Therapeutic category

Hormones-miscellaneous

Non-proprietary name

Dinoprostone

Safety measure

Precautions should be revised in the package insert.

Pharmaceuticals and Medical Devices Agency

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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
Warnings Patients should be fully informed of the necessity of labour induction and labour augmentation with this drug along with the risks associated, and this drug should be administered after their consent is obtained.	Warnings 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. Patients should be fully informed of the necessity of labour induction and labour augmentation with this drug along with the risks associated prior to administration, and administration of this drug should be initiated after their consent is obtained.
This drug is less dose-adjustable compared to its drip infusion counterparts and should be used in a setting where foetal heart rates and maternal uterine contraction status can be closely monitored with an electronic foetal monitor.	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. This drug is less dose-adjustable compared to its drip infusion counterparts and careful administration is required.

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Important Precautions This drug is less dose-adjustable compared to its drip infusion counterparts. Careful administration is required to avoid overdosing. Maternal uterine contraction status and foetal heart rates should be observed with an electronic foetal monitor with appropriate dosing intervals maintained, and administration should be discontinued when labour induction effects or labour augmentation effects are observed. 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 augmented with this drug, patients should be carefully observed by labour monitoring with an electronic foetal monitor as well as regularly checking vital signs, and appropriate measures should be taken if any abnormalities are observed.	Important Precautions This drug is less dose-adjustable compared to its drip infusion counterparts. Careful administration is required to avoid overdosing. Maternal uterine contraction status and foetal heart rates should be observed by continuous monitoring with an electronic foetal monitor with appropriate dosing intervals maintained, and administration should be discontinued when labour induction effects or labour augmentation effects are observed. 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 augmented with this drug, patients should be carefully observed by continuous monitoring with an electronic foetal monitor intended for close monitoring of maternal and foetal conditions as well as regularly checking vital signs, and appropriate measures should be taken if any abnormalities are observed. 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.

This drug is designated as a drug requiring preparation of a Drug Guide for Patients.

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
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