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Pharmaceuticals and Medical Devices Agency

Revision of PRECAUTIONS

Carvedilol

April 9, 2024

Therapeutic category

Antiarrhythmic agents

Non-proprietary name

Carvedilol

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

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Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

Current	Revision
2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) Pregnant women or women who may be pregnant 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.5 Pregnant Women This drug should not be administered to pregnant women or women who may be pregnant. A decrease in the corpus luteum count and an increase in skeletal anomalies (shortening of 13th ribs) have been reported at approximately 900-fold the clinical dose (300 mg/kg) in studies in rats before pregnancy and in early pregnancy.	2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) (deleted) 9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.5 Pregnant Women Pregnant women or women who may be pregnant should be administered this drug only if the potential therapeutic benefits are considered to outweigh the potential risks. Prior to administration of this drug, mothers and foetuses should be carefully monitored. In addition, neonates should be carefully monitored after birth. If any abnormalities such as hypoglycaemia, bradycardia, feeding intolerance, etc. are observed in neonates, appropriate measures should be taken. It has been reported that foetal growth restriction, neonatal hypoglycaemia, bradycardia, feeding intolerance, etc. were noted when pregnant women were exposed to β-blockers. In addition, a decrease in the corpus luteum count and an increase in skeletal anomalies (shortening of 13th ribs) have been reported at

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	approximately 150-fold the clinical dose (300 mg/kg) using body surface area conversion in studies in rats before pregnancy and in early pregnancy.