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Pharmaceuticals and Medical Devices Agency

Revision of PRECAUTIONS

Bisoprolol fumarate

April 9, 2024

Therapeutic category

Antiarrhythmic agents

Non-proprietary name

Bisoprolol fumarate

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. Foetal toxicity (fatality, growth inhibition) and neonatal toxicity (developmental toxicity, etc.) have been reported in animal studies (rats, rabbits).	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, foetal toxicity (fatality, growth inhibition) and neonatal toxicity (developmental toxicity, etc.) have been reported in animal studies

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	(rats, rabbits) (safety margin[note)]: 58-fold in rat foetuses, 39-fold in rabbit foetuses, and 19-fold in rat neonates). Note) The values of the safety margins were calculated by comparing the maximum clinical dose of this drug, which is 5 mg, and the no observed adverse effect level using body surface area conversion in animal studies (human equivalent dose based on body surface area conversion).