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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

## Amlodipine besilate

December 5, 2022

### **Therapeutic category**

Vasodilators

### **Non-proprietary name**

Amlodipine besilate

### **Safety measure**

Precautions should be revised.

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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>Contraindications</p> <p><u>Pregnant women or women who may be pregnant</u></p> <p>Use during Pregnancy, Delivery or Lactation</p> <p><u>This drug should not be administrated to pregnant women or women who may be pregnant.</u> [Prolongation of both the gestational period and the duration of labor was observed when this drug was administered to rats in late pregnancy.]</p>	<p>Contraindications</p> <p>(deleted)</p> <p>Use during Pregnancy, Delivery or Lactation</p> <p><u>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.</u> [Prolongation of both the gestational period and the duration of labor was observed when this drug was administered to rats in late pregnancy.]</p>

(Reference) Horimoto, M., et al.: Pharmacometrics 1991; 42(2): 167-176

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

Current	Revision
<p>2. CONTRAINDICATIONS</p> <p><u>Pregnant women or women who may be pregnant</u></p> <p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.5 Pregnant Women</p> <p><u>This drug should not be administered to pregnant women or</u></p>	<p>2. CONTRAINDICATIONS</p> <p>(deleted)</p> <p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.5 Pregnant Women</p> <p><u>Pregnant women or women who may be pregnant should be</u></p>

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