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# **Revision of PRECAUTIONS**

# Carvedilol

Aug 6, 2014

## **Non-proprietary Name**

Carvedilol

### Safety measure

Precautions should be revised in the package inserts.

In Clinically significant adverse reactions subsection of Adverse Reactions section, the following texts should be added:

Toxic epidermal necrolysis (TEN) and/or oculomucocutaneous syndrome (Stevens-Johnson syndrome):

TEN and/or oculomucocutaneous syndrome may occur. Patients should be carefully monitored. If any abnormalities are observed, administration of this drug should be discontinued, and appropriate measures should be taken.

#### NOTE

• This drug is designated to prepare a Drug Guide for Patients.

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