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.