*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.*

# Summary of investigation results

## Carvedilol

Aug 6, 2014

### Non-proprietary Name

Carvedilol

### Brand Name (Marketing Authorization Holder)

ARTIST tablets 1.25 mg, 2.5 mg, 10 mg, 20 mg, (Daiichi Sankyo Company, Limited) and the others

### Indications

- Essential hypertension (modest to moderate)
- Renal parenchymal hypertension
- Angina pectoris
- Patients who have chronic cardiac failure associated with ischaemic heart disease or dilated cardiomyopathy, and who are treated with drugs including angiotensin-converting enzyme inhibitors, diuretics, or digitalis products.

### Summary of revision

'Toxic epidermal necrolysis' and 'oculomucocutaneous syndrome' should be added in Clinically significant adverse reactions section.

### Background of the revision and investigation results

Cases of toxic epidermal necrolysis and oculomucocutaneous syndrome have been reported in patients treated with carvedilol in Japan and foreign countries and a company core datasheet (CCDS)* has been updated. Following an investigation result based on opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

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**The number of reported adverse reaction and fatal cases in the last 3 fiscal years in Japan**

A toxic epidermal necrolysis case has been reported. No causal relationship with carvedilol was established in the case. No fatality has been reported.

No oculomucocutaneous syndrome case has been reported in the last 3 fiscal years in Japan.

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NOTE

*CCDS is prepared by a marketing authorization holder and covers material relating to safety, indications, dosing, pharmacology, and other information concerning the product.

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