Summary of Investigation Results

Amiodarone hydrochloride

June 5, 2018

Non-proprietary name

Amiodarone hydrochloride

Branded name (Marketing authorization holder)

a. Ancaron tab. 100 (Sanofi K.K.), and the others

b. Ancaron inj. 150 (Sanofi K.K.), and the others

Indications

a.

Treatment of the following life-threatening recurrent ventricular arrhythmias, when these conditions have not responded to other available arntiarrhythmics or when alternative agents could not be used:

Ventricular fibrillation, ventricular tachycardia, heart failure (impaired cardiac function), or atrial fibrillation associated with hypertrophic cardiomyopathy

b.

・Treatment of the following life-threatening arrhythmias, when these are refractory and require emergency treatment:

Ventricular fibrillation, hemodynamically unstable ventricular tachycardia

・Electrical cardioversion-resistant ventricular fibrillation or cardiac arrest due to pulseless ventricular tachycardia

Summary of revision

“Agranulocytosis, leukopenia” should be added to the Clinically Significant Adverse Reactions section.

Pharmaceuticals and Medical Devices Agency
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Investigation results and background of the revision

Cases of agranulocytosis and/or leukopenia have been reported in patients treated with amiodarone hydrochloride in Japan. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of the currently available evidence and in consultation with expert advisors.

Number of adverse reactions and patient mortalities reported in Japan during the previous 3 fiscal years

A total of 3 cases involving agranulocytosis and/or leukopenia have been reported to date (including 1 case for which a causal relationship with the product could not be ruled out.)
No patient mortalities have been reported to date.

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