This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of Investigation Results

Adenosine

October 12, 2023

Non-proprietary name

Adenosine

Brand name (marketing authorization holder)

Adenoscan Injection 60 mg (Daiichi Sankyo Co., Ltd.), and the others

Japanese market launch

June 2005

Indications

Load induction to make a diagnosis of heart disease based on myocardial perfusion scintigraphy in patients unable to tolerate sufficient exercise load

Summary of revisions

“Anaphylaxis” should be added to the Clinically Significant Adverse Reactions section in ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving anaphylaxis were evaluated. Cases for which a causal relationship between adenosine and anaphylaxis was reasonably possible have been reported. As a result of consultation with expert advisors regarding the causality assessment of the cases and the necessity of revision of PRECAUTIONS, the MHLW/PMDA concluded that revision of PRECAUTIONS was necessary.

Reference: Number of cases* and patient mortalities involving anaphylaxis reported

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in Japan and overseas

A total of 6 cases have been reported in Japan to date (including 4 cases for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported in Japan to date.

A total of 6 cases have been reported overseas to date (including 2 cases for which a causal relationship between the drug and event was reasonably possible).

One instance of patient mortality has been reported overseas to date. (A causal relationship between the drug and death subsequent to the event could not be established for this case.)

*Cases collected in the PMDA's database for adverse drug reactions, etc. reports

The expert advisors present at the Expert Discussion regarding the current investigation were nominated based on their conflict of interest declarations concerning the relevant products, pursuant to the “Rules for Convening Expert Discussions, etc., by the Pharmaceuticals and Medical Devices Agency” (PMDA Administrative Rule No. 20-8, dated December 25, 2008).

Pharmaceuticals and Medical Devices Agency

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