



# Summary of Investigation Results

## Technetium ( $^{99m}\text{Tc}$ ) tetrofosmin

October 12, 2023

### Non-proprietary name

Technetium ( $^{99m}\text{Tc}$ ) tetrofosmin

### Brand name (marketing authorization holder)

Myoview Kit, Myoview Injection (Nihon Medi-Physics Co., Ltd.)

### Japanese market launch

Myoview Kit: April 1994

Myoview Injection 296 MBq, 592 MBq: January 1997

Myoview Injection 740 MBq: January 1998

### Indications

Diagnosis of heart disease based on myocardial scintigraphy, diagnosis of cardiac function by first-transit study

### Summary of revisions

1. The CONTRAINDICATIONS (This drug is contraindicated to the following patients.) section should be newly added, and “patients with a history of hypersensitivity to ingredients of this drug” should be added.
2. The Clinically Significant Adverse Reactions section in ADVERSE REACTIONS should be newly added, and “shock, anaphylaxis” should be added.

### Investigation results and background of the revision

Cases involving anaphylaxis were evaluated. Cases for which a causal relationship between technetium ( $^{99m}\text{Tc}$ ) tetrofosmin and shock or anaphylaxis was reasonably possible

Pharmaceuticals and Medical Devices Agency



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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 in Japan and overseas**

A total of 2 cases have been reported in Japan to date. (A causal relationship between the drug and event was reasonably possible for these cases.)

No patient mortalities have been reported in Japan to date.

A total of 13 cases have been reported overseas to date (including 8 cases for which a causal relationship between the drug and event was reasonably possible).

No patient mortalities have been reported overseas to date.

\*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).