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

Technetium (^{99m}Tc) galactosyl human serum albumin diethylenetriamine pentaacetic acid

November 21, 2023

Non-proprietary name

Technetium (^{99m}Tc) galactosyl human serum albumin diethylenetriamine pentaacetic acid

Brand name (marketing authorization holder)

Asialoscinti Injection (Nihon Medi-Physics Co., Ltd.)

Japanese market launch

August 1992

Indications

Diagnosis of the function and form of the liver based on scintigraphy

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}Tc) galactosyl human serum albumin diethylenetriamine

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp

pentaacetic acid and shock or 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 in Japan

A total of 4 cases involving anaphylaxis have been reported to date. (A causal relationship between the drug and event was reasonably possible for these cases.)
No patient mortalities have been reported 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).

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan
E-mail: safety.info@pmda.go.jp