



Summary of investigation results

Technetium(99mTc) hydroxymethylenediphosphonate injection, Kit for the preparation of technetium(99mTc) hydroxymethylene-diphosphonate injection

June 2, 2015

Non-proprietary name

- a. technetium (99mTc) hydroxymethylenediphosphonate injection
- b. kit for the preparation of technetium (99mTc) hydroxymethylenediphosphonate injection

Brand name (Marketing authorization holder)

- a. Clearbone Injectable (Nihon Medi-Physics Co., Ltd.)
- b. Clearbone Kit (Nihon Medi-Physics Co., Ltd.)

Indications

a and b

Diagnosis of bone diseases by scintigraphic imaging of the bone

Summary of revision

a and b

- “CONTRAINDICATIONS” section should be newly added in the package insert. In addition, “Patients with a history of hypersensitivity to any ingredients of this product” should be added in the new Contraindications section.
- “Clinically Significant Adverse Reactions” section should be newly added in the package insert. In addition, “Shock and anaphylaxis” should be added in the new Clinically significant adverse reactions section.



Background of the revision and investigation results

Cases of shock and anaphylaxis have been reported in patients treated with these products in Japan. Following an investigation based on the opinions of expert advisors and available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

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

- a. A shock or anaphylaxis case has been reported (Including a case for which a causal relationship to the product could not be ruled out). No fatality has been reported.
- b. A shock or anaphylaxis case has been reported (The causal relationship to the product could be ruled out for the patient). No fatality has been reported.