



Summary of Investigation Results

Aminolevulinic acid hydrochloride

February 25, 2020

Non-proprietary name

Aminolevulinic acid hydrochloride

Branded name (Marketing authorization holder)

- a. Alaglio Divided Granules 1.5 g (SBI Pharmaceuticals Co., Ltd.)
- b. Alabel Oral 1.5g (Nobelpharma Co., Ltd.)

Indications

- a. Visualization of non-muscle invasive bladder cancer during transurethral resection of the bladder tumor
- b. Visualization of malignant tissue during malignant glioma resection

Summary of revisions

“Hypotension” should be added to the Clinically Significant Adverse Reactions section.

Investigation results and background of the revision

Cases of hypotension have been reported in patients treated with aminolevulinic acid hydrochloride in Japan. MHLW/PMDA in consultation with expert advisors concluded that revision of the package insert was necessary.



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

Cases involving hypotension

- a. A total of 24 cases have been reported to date (including 15 cases for which a causal relationship between the drug and event could not be ruled out). No patient mortalities have been reported to date.
(Japanese market launch: December 2017)
- b. A total of 2 cases have been reported to date (A causal relationship between the drug and event could not be established in either of these cases.) No patient mortalities have been reported to date.

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).