



Summary of Investigation Results

Acetazolamide Acetazolamide sodium

January 10, 2024

Non-proprietary name

- a. Acetazolamide
- b. Acetazolamide sodium

Brand name (marketing authorization holder)

- a. Diamox Powder, Diamox Tablets 250 mg (Sanwa Kagaku Kenkyusho Co., Ltd.)
- b. Diamox for Injection 500 mg (Sanwa Kagaku Kenkyusho Co., Ltd.)

Japanese market launch

- a. (Powder) August 1958 (Tablets) March 1955
- b. December 1963

Indications

- a. (Powder) Glaucoma, epilepsy (to be added when other antiepileptics are not sufficiently effective), improvement of respiratory acidosis in emphysema, cardiac induced oedema, hepatic induced oedema, premenstrual tension, Meniere's disease and syndrome
(Tablets) Glaucoma, epilepsy (to be added when other antiepileptics are not sufficiently effective), improvement of respiratory acidosis in emphysema, cardiac induced oedema, hepatic induced oedema, premenstrual tension, Meniere's disease and syndrome, sleep apnoea syndrome
- b. Glaucoma, epilepsy (to be added when other antiepileptics are not sufficiently effective), improvement of respiratory acidosis in emphysema, Meniere's disease

Pharmaceuticals and Medical Devices Agency

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

and syndrome

Summary of revisions

“Acute respiratory distress syndrome, pulmonary oedema” should be added to the Clinically Significant Adverse Reactions section in ADVERSE REACTIONS.

Investigation results and background of the revision

Cases involving acute respiratory distress syndrome and pulmonary oedema were evaluated. Cases for which a causal relationship of acetazolamide or acetazolamide sodium to acute respiratory distress syndrome or pulmonary oedema 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 acute respiratory distress syndrome and pulmonary oedema reported in Japan and overseas

- a. A total of 3 cases have been reported in Japan to date.
 - <Causality assessment as acute respiratory distress syndrome>
A causal relationship between the drug and event was reasonably possible for 2 of the 3 cases.
No patient mortalities have been reported in Japan to date.
 - <Causality assessment as pulmonary oedema>
A causal relationship between the drug and event was reasonably possible for 2 of the 3 cases.)
No patient mortalities have been reported in Japan to date.
- A total of 6 cases have been reported overseas to date.
 - <Causality assessment as acute respiratory distress syndrome>
A causal relationship between the drug and event was reasonably possible for 4 of the 6 cases, including 1 case which fell under the contraindications.
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.)

<Causality assessment as pulmonary oedema>

A causal relationship between the drug and event was reasonably possible for 4 of the 6 cases, including 1 case which fell under the contraindications.

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.)

b. A total of 8 cases have been reported in Japan to date.

<Causality assessment as acute respiratory distress syndrome>

A causal relationship between the drug and event was reasonably possible for 7 of the 8 cases, including 6 cases in which the drug was administered outside the approved indications.

A total of 3 patient mortalities have been reported in Japan to date. (A causal relationship between the drug and deaths subsequent to the event could not be established for any of these cases.)

<Causality assessment as pulmonary oedema>

A causal relationship between the drug and event was reasonably possible for 7 of the 8 cases, including 6 cases in which the drug was administered outside the approved indications.

A total of 3 patient mortalities have been reported in Japan to date. (A causal relationship between the drug and deaths subsequent to the event could not be established for any of these cases.)

No cases have been reported overseas to date.

*Cases collected in the PMDA's database for adverse drug reactions, etc. reports
Cases reported as adverse drug reaction name (PT) "acute respiratory distress syndrome," "acute pulmonary oedema," "pulmonary oedema," and "non-cardiogenic pulmonary oedema" were retrieved.

Considering possibilities such as assessment of acute respiratory distress syndrome being difficult due to lack of diagnostic information but assessment of pulmonary oedema being



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possible in some of the cases, a causality assessment of the retrieved cases was conducted as "acute respiratory distress syndrome" and "pulmonary oedema," respectively.

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).