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Summary of Investigation Results

Calcium gluconate hydrate Calcium chloride hydrate (injection excluding preparations indicated for electrolyte correction in electrolyte replacement fluids)

April 21, 2026

Non-proprietary name

- a. Calcium gluconate hydrate
- b. c. Calcium chloride hydrate (injection)

Brand name (marketing authorization holder)

- a. Calciol Injection 8.5% 5 mL, 10 mL (Nichi-Iko Pharmaceutical Co., Ltd.)
- b. Otsuka Calcium Chloride Injection 2% (Otsuka Pharmaceutical Factory, Inc.)
- c. Calcium Chloride Injection 2% "NP" (Nipro Corporation)

Japanese market launch

- a. 1928
- b. October 1992
- c. May 1974

Indications

- a.
 - Improvement of the following symptoms caused by hypocalcaemia
Tetany, tetany related symptoms
 - Supplementation of calcium in celiac disease
- b. c.

Pharmaceuticals and Medical Devices Agency



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- Improvement of the following symptoms caused by hypocalcaemia
Tetany, tetany related symptoms
- Lead poisoning
- Magnesium poisoning
- Calcium supplementation in the following metabolic bone diseases:
Osteomalacia in pregnant women/parturient women

Summary of revisions

a.

1. "Patients receiving cardiac glycosides" in 2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) section should be deleted.
2. Cardiac glycosides should be deleted from the 10.1 Contraindications for Co-administration (Do not co-administer with the following.) section in 10. INTERACTIONS.
3. Cardiac glycosides should be added to the 10.2 Precautions for Co-administration (This drug should be administered with caution when co-administered with the following.) section in 10. INTERACTIONS.

b. c.

1. "Patients receiving digitalis preparations (digoxin, etc.)" in the 2. CONTRAINDICATIONS (This drug is contraindicated to the following patients.) section should be deleted.
2. Digitalis preparations should be deleted from the 10.1 Contraindications for Co-administration (Do not co-administer with the following.) section in 10. INTERACTIONS.
3. Cardiac glycosides should be added to the 10.2 Precautions for Co-administration (This drug should be administered with caution when co-administered with the following.) section in 10. INTERACTIONS.

Investigation results and background of the revision

Regarding co-administration of calcium gluconate hydrate or calcium chloride hydrate (injection) with cardiac glycosides, how precautions have been described in overseas labeling, Japanese and overseas guidelines, books, and published literature was investigated. As a result of consultation with expert advisors, the MHLW/PMDA concluded that it was necessary to revise PRECAUTIONS to specify co-administration with cardiac glycosides in Precautions for Co-administration instead of Contraindications for Co-administration for the following reasons.



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- Japanese and overseas guidelines, books, and other sources have not specified co-administration with cardiac glycosides as contraindications for co-administration.
- As a result of review of the overseas (US, UK) labeling of calcium gluconate hydrate, co-administration with cardiac glycosides is not contraindicated in the US labeling. In the UK labeling, co-administration with cardiac glycosides is contraindicated, but the exceptional use is allowed in the case where patients with severe hypocalcaemia or acute severe hyperkalaemia are in a life-threatening state. The marketing of calcium chloride hydrate (Injection 2%) has not been confirmed in Europe and the US.
- In clinical settings, calcium injection is expected to be used for the treatment of hyperkalaemia or hypocalcaemia in patients with conditions such as digitalis intoxication, and situations in which administration of calcium injection is required even during use of cardiac glycosides are expected.

To minimize the risk of occurrence of symptoms such as serious arrhythmia resulting from co-administration with cardiac glycosides, the MHLW/PMDA concluded that the descriptions to the effect that the co-administration should be avoided unless it is considered therapeutically essential and if co-administration is inevitable, monitoring using an electrocardiogram, etc. should be performed to deal with the occurrence of arrhythmia and that usage in such a way as to rapidly increase calcium concentration should be avoided should be added to the column for signs, symptoms, and treatment.

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).