

This document is an English-translated version of an attachment of a notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

This English version is intended to be a reference material to provide convenience for users.

In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Revision of PRECAUTIONS

Ethical combination drugs

(Brand name: Twinpal Injection, Plas-Amino Injection)

L-arginine hydrochloride

(Brand name: Argi-U Injection 20 g)

January 29, 2025

Therapeutic category

Proteins, amino acid and preparations

Agents affecting metabolism, n.e.c. (not elsewhere classified)

Non-proprietary name

Not applicable to ethical combination drugs

L-arginine hydrochloride

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complication or History of Diseases, etc. (N/A)	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.1 Patients with Complication or History of Diseases, etc. <u>Patients with a history of hypersensitivity to any of the ingredients of this drug</u> <u>This drug should not be administered except in cases where such use is considered absolutely necessary for the treatment.</u> <u>Anaphylaxis may occur.</u>
11. ADVERSE REACTIONS (N/A)	11. ADVERSE REACTIONS <u>11.1 Clinically Significant Adverse Reactions</u> <u>Anaphylaxis</u>

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.