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Translated by
Pharmaceuticals and Medical Devices Agency



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

Enviomycin sulfate, Cycloserine, Aluminoparaaminosalicylate calcium hydrate, Isoniazid, Isoniazid sodium methanesulfonate hydrate, Ethionamide, Calcium paraaminosalicylate hydrate, Pyrazinamide, Bedaquiline fumarate

March 23, 2023

Therapeutic category

Antibiotic preparations acting mainly on acid-fast bacteria

Anti-tuberculous agents

Pharmaceuticals and Medical Devices Agency

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Non-proprietary name

Enviomycin sulfate

Cycloserine

Aluminoparaaminosalicylate calcium hydrate

Isoniazid

Isoniazid sodium methanesulfonate hydrate

Ethionamide

Calcium paraaminosalicylate hydrate

Pyrazinamide

Bedaquiline fumarate

Safety measure

Precautions should be revised.

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Revision in line with the Instructions for Package Inserts of Prescription Drugs, PAB Notification No. 606 by the Director General of Pharmaceutical Affairs Bureau, MHW, dated April 25, 1997 (Old instructions): Revised language is underlined.

Current	Revision
Important Precautions (N/A)	Important Precautions <u>A paradoxical drug reaction may be observed due to the treatment with antitubercular agents including this drug. If worsening of existing tuberculosis or new onset of tuberculosis symptoms is observed after initiating the treatment, whether to continue administration should be determined on the basis of drug susceptibility tests, etc.</u>

Note: Enviomycin sulfate, isoniazid, and isoniazid sodium methanesulfonate hydrate are designated as drugs requiring preparation of a Drug Guide for Patients.

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

Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. PSEHB Notification No. 0611-1 by the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions): Revised language is underlined.

Current	Revision
8. IMPORTANT PRECAUTIONS (N/A)	8. IMPORTANT PRECAUTIONS <u>A paradoxical drug reaction may be observed due to the treatment with antitubercular agents including this drug. If worsening of existing tuberculosis or new onset of tuberculosis symptoms is observed after initiating the treatment, whether to continue administration should be determined on the basis of drug susceptibility tests, etc.</u>

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