Published by Ministry of Health, Labour and Welfare 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

Metyrapone

November 21, 2023

Therapeutic category

Other hormone preparations (including antihormone preparations) Reagents for various function tests

62

Non-proprietary name

Metyrapone

Safety measure PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan E-mail: <u>safety.info@pmda.go.jp</u> Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, PSEHB Notification No. 0611-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, MHLW, dated June 11, 2021 (New instructions):

Revised language is underlined.

	5 5
Current	Revision
8. IMPORTANT PRECAUTIONS	8. IMPORTANT PRECAUTIONS
<cushing's syndrome=""></cushing's>	<cushing's syndrome=""></cushing's>
(N/A)	Prolonged QT may occur. An electrocardiogram test should be
	performed as necessary.
(N/A)	Hypokalaemia may occur. Patients should be carefully monitored through methods such as performing tests.
11. ADVERSE REACTIONS	11. ADVERSE REACTIONS
11.2 Other Adverse Reactions	11.2 Other Adverse Reactions
Circulation Hypotension, hypertension	Circulation Hypotension, hypertension, prolonged QT
(N/A) (N/A)	Metabolism Hypokalaemia

Note: Designated as a drug requiring preparation of a Drug Guide for Patients

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

Pharmaceuticals and Medical Devices Agency

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