Published by Ministry of Health, Labour and Welfare

62

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 Metronidazole (injections)

June 14, 2022

Therapeutic category

Antiprotozoan agents

Non-proprietary name

Metronidazole

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, 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 |
|---|---|
| 11. ADVERSE REACTIONS | 11. ADVERSE REACTIONS |
| 11.1 Clinically Significant Adverse Reactions | 11.1 Clinically Significant Adverse Reactions |
| (N/A) | Prolonged QT, ventricular tachycardia (including torsade de |
| | pointes) |

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>