

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

## Hydroxychloroquine sulfate

January 17, 2023

### **Therapeutic category**

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

### **Non-proprietary name**

Hydroxychloroquine sulfate

### **Safety measure**

Precautions should be revised.

**Pharmaceuticals and Medical Devices Agency**

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan  
E-mail: [safety.info@pmda.go.jp](mailto:safety.info@pmda.go.jp)

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
<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), erythema multiforme, erythroderma (exfoliative dermatitis), drug-induced hypersensitivity syndrome, acute generalised exanthematous pustulosis</p>	<p>11. ADVERSE REACTIONS</p> <p>11.1 Clinically Significant Adverse Reactions</p> <p>Toxic epidermal necrolysis (TEN), oculomucocutaneous syndrome (Stevens-Johnson syndrome), erythema multiforme, erythroderma (exfoliative dermatitis), drug-induced hypersensitivity syndrome, acute generalised exanthematous pustulosis, <u>acute febrile neutrophilic dermatosis (Sweet's syndrome)</u></p>

**Pharmaceuticals and Medical Devices Agency**

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan  
 E-mail: [safety.info@pmda.go.jp](mailto:safety.info@pmda.go.jp)