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# Revision of PRECAUTIONS

## Minocycline hydrochloride (oral dosage form, injections)

July 20, 2023

### Therapeutic category

Antibiotic preparations acting mainly on gram-positive, gram-negative bacteria, and rickettsia and chlamydia

### Non-proprietary name

Minocycline hydrochloride

### Safety measure

PRECAUTIONS should be revised.

**Pharmaceuticals and Medical Devices Agency**

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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 |
|---|---|
| Adverse Reactions<br>Clinically Significant Adverse Reactions<br>Exacerbation of systemic lupus erythematosus (SLE)-like symptoms:<br>Exacerbation of systemic lupus erythematosus (SLE)-like symptoms may occur. If these symptoms occur, administration of this drug should be discontinued, and appropriate measures should be taken. | Adverse Reactions<br>Clinically Significant Adverse Reactions<br>Lupus-like syndrome:<br>Lupus-like syndrome may occur. If these symptoms occur, administration of this drug should be discontinued, and appropriate measures should be taken. Cases have been reported more frequently, especially in long-term treatment cases where this drug has been used for more than 6 months. |

Revision in line with the Instructions for Electronic Package Inserts of Prescription Drugs, etc. 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.

| Current | Revision |
|---|---|
| 11. ADVERSE REACTIONS<br>11.1 Clinically Significant Adverse Reactions<br>Exacerbation of systemic lupus erythematosus (SLE)-like symptoms | 11. ADVERSE REACTIONS<br>11.1 Clinically Significant Adverse Reactions<br>Lupus-like syndrome<br>Cases have been reported more frequently, especially in long-term treatment cases where this drug has been used for more than 6 months. |

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