

This document is an English-translated version of an attachment of notification for Revision of PRECAUTIONS issued by the Ministry of Health, Labour and Welfare.

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

Carglumic acid

June 11, 2024

Therapeutic category

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

Non-proprietary name

Carglumic acid

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revision
<p>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p><Common to all indications></p> <p>(N/A)</p>	<p>7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION</p> <p><Common to all indications></p> <p><u>The starting dose should be reduced in patients with moderate or severe renal impairment. It is recommended to start administration referring to the following: 50 mg to 125 mg per kg of body weight per day in patients with moderate renal impairment (eGFR greater than or equal to 30 and less than 60 mL/min/1.73 m²); 15 mg to 40 mg per kg of body weight per day in patients with severe renal impairment (eGFR less than 30 mL/min/1.73 m²).</u></p>
<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>(N/A)</p>	<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p><u>9.2 Patients with Renal Impairment</u></p> <p><u>Patients with moderate or severe renal impairment (eGFR less than 60 mL/min/1.73 m²)</u></p> <p><u>The starting dose should be reduced. The blood concentration of this drug may increase due to delayed renal excretion.</u></p>

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.