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
7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION <Common to all indications> (N/A)	7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION <Common to all indications> 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 m^2); 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 m^2).
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS (N/A)	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.2 Patients with Renal Impairment Patients with moderate or severe renal impairment (eGFR less than 60 mL/min/1.73 m^2) The starting dose should be reduced. The blood concentration of this drug may increase due to delayed renal excretion.

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.