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.
<table>
<thead>
<tr>
<th>Current</th>
<th>Revision</th>
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| 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 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). |
| 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 m²)  
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.