Revision of PRECAUTIONS

Imeglimin hydrochloride

April 8, 2025

Therapeutic category

Antidiabetic agents

Non-proprietary name

Imeglimin hydrochloride

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

<table>
<tr><th>Current</th><th>Revision</th></tr>
<tr><td>5.PRECAUTIONS CONCERNING INDICATIONS
In patients with renal impairment, the excretion of this drug from the kidneys is delayed depending on the degree of renal impairment and the blood concentration of this drug is increased. No clinical studies have been conducted to evaluate the efficacy and safety of this drug in patients with moderate or severe (eGFR less than 45 mL/min/1.73 m^2) renal impairment, and administration of this drug is not recommended.

(N/A)</td><td>5.PRECAUTIONS CONCERNING INDICATIONS
(deleted)

7. PRECAUTIONS CONCERNING DOSAGE AND ADMINISTRATION
Since the blood concentration of this drug increases due to delayed excretion of this drug in patients with renal impairment, attention should be paid to the following points:
•In patients whose eGFR is greater than 10 mL/min/1.73 m^2 and less than 45 mL/min/1.73 m^2, the dose and dosing interval should be adjusted according to the table below.
<table>
<tr><th>eGFR
(mL/min/1.73 m^2)</th><th>Dosing regimen</th></tr>
<tr><td>15 ≤ eGFR < 45</td><td>A dose of 500 mg, twice daily in the morning and evening</td></tr>
<tr><td>10 ≤ eGFR <15</td><td>A dose of 500 mg, once daily</td></tr>
</table>
•In particular, this drug should be administered to patients whose eGFR is greater than 10 mL/min/1.73 m^2 and less than 15 mL/min/1.73 m^2 only if the potential therapeutic benefits are</td></tr>
</table>

	considered to outweigh the potential risks. During administration of this drug, patients should be carefully monitored for their conditions. If further aggravation of renal function, etc. are observed, discontinuation of administration should be considered. •Administration of this drug to patients whose eGFR is less than 10 mL/min/1.73 m^2 (including dialysis patients) is not recommended.
8. IMPORTANT PRECAUTIONS Periodic renal function tests are recommended since the excretion of this drug may be delayed and the blood concentration of this drug may be increased.	8. IMPORTANT PRECAUTIONS Periodic renal function tests are recommended since the excretion of this drug is delayed and the blood concentration of this drug is increased. In particular, patients whose eGFR is less than 15 mL/min/1.73 m^2 should undergo frequent renal function testing and be closely monitored for the clinical course.
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.2 Patients with renal impairment Patients with renal impairment whose eGFR is less than 45 mL/min/1.73 m^2 (including dialysis patients) Administration of this drug is not recommended. The blood concentration of this drug may be increased markedly.	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.2 Patients with renal impairment Patients with renal impairment whose eGFR is less than 10 mL/min/1.73 m^2 (including dialysis patients) Administration of this drug is not recommended. The blood concentration of this drug may be increased markedly.
(N/A)	Patients with renal impairment whose eGFR is greater than 10 mL/min/1.73 m^2 and less than 45 mL/min/1.73 m^2 The dose and the dosing interval should be adjusted according to the degree of renal impairment. In particular, this drug should be

	administered to patients whose eGFR is greater than 10 mL/min/1.73 m^2 and less than 15 mL/min/1.73 m^2 only if the potential therapeutic benefits are considered to outweigh the potential risks. Blood concentration of this drug will be increased.

N/A: Not Applicable. No corresponding language is included in the current PRECAUTIONS.