

This document is an English-translated version of an attachment of a 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

Daprodustat

July 17, 2024

Therapeutic category

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

Non-proprietary name

Daprodustat

Safety measure

PRECAUTIONS should be revised.

Pharmaceuticals and Medical Devices Agency

3-3-2 Kasumigaseki, Chiyoda-ku, Tokyo 100-0013 Japan

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Revised language is underlined.

Current	Revision
<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.1 Patients with Complication or History of Diseases, etc. (N/A)</p>	<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.1 Patients with Complication or History of Diseases, etc.</p> <p><u>Patients with cardiac failure or a history of the disease</u></p> <p><u>Exacerbation or relapse of cardiac failure may occur. The results of subgroup analyses for patients with cardiac failure or a history of the disease, which were conducted as post-hoc analyses of overseas clinical studies, were as follows: In the clinical study in patients with chronic kidney disease on dialysis, the incidence ratio of the first hospitalization for cardiac failure was 17.6% (47/267 cases) for the daprodustat group and 12.6% (32/254 cases) for the erythropoietin stimulating agents group with a hazard ratio of 1.52 (95% CI: 0.97–2.38); in the clinical study in patients with chronic kidney disease not on dialysis, the incidence ratio was 20.4% (54/265 cases) for the daprodustat group and 13.4% (34/254 cases) for the erythropoietin stimulating agents group with a hazard ratio of 1.37 (95% CI: 0.89–2.11). Thus, the ratios for the daprodustat group tended to be higher in both clinical studies.</u></p>

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

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