

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

TAVNEOS[®] Capsules 10mg

May 21, 2026

Therapeutic category

Agents affecting metabolism,nec

Non-proprietary name

Avacopan

Safety measure

PRECAUTIONS should be revised.

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Revised description is underlined.

Current	Revision
<p>(N/A)</p> <p>8. IMPORTANT PRECAUTIONS</p> <p>Since hepatic dysfunction may occur, <u>patients should be closely monitored through hepatic function tests before the start of treatment with this drug and periodically during treatment.</u></p> <p>(N/A)</p>	<p><u>1. Warnings</u></p> <p><u>Serious hepatic dysfunction, including vanishing bile duct syndrome, may occur, and fatal cases have been reported. Patients should be carefully monitored through periodic hepatic function tests before and during treatment with this drug. If serious hepatic dysfunction is observed during treatment with this drug, appropriate measures, such as discontinuation of treatment with this drug, should be taken.</u></p> <p>8. IMPORTANT PRECAUTIONS</p> <p>Since hepatic dysfunction may occur, <u>careful attention should be paid to the following points. In most cases, hepatic dysfunction has been reported in the first 3 months of treatment with this drug.</u></p> <p><u>Patients should be closely monitored through hepatic function tests before the start of treatment with this drug, at least once every 2 weeks during the first 3 months of treatment, at least once every 4 weeks during the next 3 months of treatment, and periodically during treatment thereafter.</u></p> <p><u>If ALT or AST >3 times upper limit of normal is observed during treatment with this drug, treatment should be interrupted and patients should be assessed immediately. In addition, treatment with this drug should be discontinued in the following cases:</u></p> <ul style="list-style-type: none"> <u>- ALT or AST >8 times upper limit of normal</u> <u>- ALT or AST >5 times upper limit of normal for more than 2 weeks</u> <u>- Total bilirubin >2 times upper limit of normal</u> <u>- ALP ≥2 times upper limit of normal</u> <u>- Presence of signs or symptoms of hepatic dysfunction such as jaundice and pruritus</u> <p><u>Treatment with this drug should be discontinued immediately if vanishing bile duct syndrome is suspected.</u></p>

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