

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

Aspirin

(preparations indicated for antipyresis/analgesia/anti-inflammation)

October 8, 2024

Therapeutic category

Antipyretics, analgesics and anti-inflammatory agents

Non-proprietary name

Aspirin (preparations indicated for antipyresis/analgesia/anti-inflammation)

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revised
<p data-bbox="226 261 1111 339">9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p data-bbox="226 357 506 387">9.5 Pregnant Women</p> <p data-bbox="226 405 1111 483">Pregnant women (excluding those within 12 weeks before due date) or women who may be pregnant</p> <p data-bbox="226 501 819 531"><Indications other than Kawasaki's disease></p> <p data-bbox="226 549 1111 675">If administration is deemed necessary, caution should be exercised such as limiting the drug to the minimum effective use and checking amniotic fluid volume as necessary.</p>	<p data-bbox="1111 261 2000 339">9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p data-bbox="1111 357 1391 387">9.5 Pregnant Women</p> <p data-bbox="1111 405 2000 483">Pregnant women (excluding those within 12 weeks before due date) or women who may be pregnant</p> <p data-bbox="1111 501 1704 531"><Indications other than Kawasaki's disease></p> <p data-bbox="1111 549 2000 970">If administration is deemed necessary, caution should be exercised such as limiting the drug to the minimum effective use and checking amniotic fluid volume <u>and findings suggestive of constriction of the foetal ductus arteriosus with consideration given to the gestational age and duration of administration</u> as necessary. <u>It has been reported that constriction of the foetal ductus arteriosus occurred in pregnant women who had been administered cyclooxygenase inhibitors (preparations with expected systemic effects) in their second trimester of pregnancy.</u></p>