

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

Ethenzamide Sulpyrine hydrate

October 8, 2024

Therapeutic category

Antipyretics, analgesics and anti-inflammatory agents

Non-proprietary name

Ethenzamide

Sulpyrine hydrate

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revised
<p data-bbox="226 255 1108 335">9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p data-bbox="226 351 504 391">9.5 Pregnant Women</p> <p data-bbox="226 399 1108 821">Pregnant women or women who may be pregnant This drug should be administered only when the therapeutic benefits are considered to outweigh the risks. 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. Renal impairment and decreased urine output in foetuses as well as accompanying oligohydramnios have been reported following use of cyclooxygenase inhibitors (oral dosage form or suppository) in pregnant women.</p>	<p data-bbox="1120 255 2004 335">9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p data-bbox="1120 351 1400 391">9.5 Pregnant Women</p> <p data-bbox="1120 399 2004 1157">Pregnant women or women who may be pregnant This drug should be administered only when the therapeutic benefits are considered to outweigh the risks. 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. Renal impairment and decreased urine output in foetuses as well as accompanying oligohydramnios have been reported following use of cyclooxygenase inhibitors (oral dosage form or suppository) in pregnant women. <u>It has been reported that constriction of the foetal ductus arteriosus occurred in pregnant women who had been administered cyclooxygenase inhibitors in their second and/or third trimester of pregnancy with a higher risk known in women exposed to the drug in their third trimester.</u></p>