

*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

## Diclofenac etalhyaluronate sodium

October 8, 2024

### **Therapeutic category**

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

### **Non-proprietary name**

Diclofenac etalhyaluronate sodium

### **Safety measure**

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revised
<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.5 Pregnant Women</p> <p>Pregnant women or women who may be pregnant should be administered this drug only if the potential therapeutic benefits are considered to outweigh the potential risks. 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. It has been reported that constriction of the foetal ductus arteriosus occurred in pregnant women who had been administered <u>other dermatologic preparations of NSAIDs</u> in their third trimester of pregnancy.</p>	<p>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.5 Pregnant Women</p> <p>Pregnant women or women who may be pregnant should be administered this drug only if the potential therapeutic benefits are considered to outweigh the potential risks. 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. It has been reported that constriction of the foetal ductus arteriosus occurred in pregnant women who had been administered <u>cyclooxygenase inhibitors</u> in their <u>second and/or</u> third trimester of pregnancy.</p>