

*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

## Dibucaine hydrochloride/sodium salicylate/calcium bromide

October 8, 2024

### **Therapeutic category**

Antipyretics, analgesics and anti-inflammatory agents

### **Non-proprietary name**

Dibucaine hydrochloride/sodium salicylate/calcium bromide

### **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>&lt;Epidural block, infiltration/conduction block (trigger point injection, etc.)&gt;</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. 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>9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS</p> <p>9.5 Pregnant Women</p> <p>&lt;Epidural block, infiltration/conduction block (trigger point injection, etc.)&gt;</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. 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 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>