Revision of PRECAUTIONS

Dibucaine hydrocholoride/sodium salicylate/calcium bromide

October 8, 2024

Therapeutic category

Antipyretics, analgesics and anti-inflammatory agents

Non-proprietary name

Dibucaine hydrocholoride/sodium salicylate/calcium bromide

Safety measure

PRECAUTIONS should be revised.

Revised language is underlined.

Current	Revised
9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.5 Pregnant Women <Epidural block, infiltration/conduction block (trigger point injection, etc.)> 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.	9. PRECAUTIONS CONCERNING PATIENTS WITH SPECIFIC BACKGROUNDS 9.5 Pregnant Women <Epidural block, infiltration/conduction block (trigger point injection, etc.)> 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>