



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 sodium (oral, suppository, enema ointment)

Non-proprietary name

Diclofenac sodium (oral, suppository, enema ointment)

Safety measure

Precautions should be revised in the package insert.

In the Clinically significant adverse reaction subsection of the Adverse reaction section, the following text should be added (underlined parts are revised):

Gastrointestinal stenosis / obstruction (stenosis or obstruction may occur in association with gastrointestinal ulcer).

Note

Oral formula of diclofenac sodium is designated as a drug requiring preparation of a Drug Guide for Patients.