This English version is intended to be a reference material for the convenience of users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Summary of investigation results

Diclofenac sodium (oral, suppository, enema ointment)

Non-proprietary name

Diclofenac sodium (oral, suppository, enema ointment)

Brand name (Marketing authorization holder)

(1) Voltaren Tablets 25 mg (Novartis Pharma K.K.), and others
(2) Voltaren SUPPO 12.5 mg, 25 mg, 50 mg (Novartis Pharma K.K.), Rectos enema ointment 25 mg, 50 mg (Nichi-Iko Pharmaceutical Co., Ltd.), and others
(3) Voltaren SR Capsules 37.5 mg (Dojin Iyaku-Kako Co., Ltd.), and others

Indications

(1)

- Relief of pain and anti-inflammation in the following diseases and symptoms:
  Rheumatoid arthritis, osteoarthritis, spinal osteoarthritis, low back pain, tenosynovitis, neck, shoulder and arm syndrome, neuralgia, afterbirth pain, pelvic inflammation, dysmenorrhea, cystitis, anterior eye inflammation, toothache
- Relief of pain and anti-inflammation after surgery and tooth extraction
- Antipyresis and relief of pain in the following diseases:
  Acute upper respiratory inflammation (including acute upper respiratory inflammation accompanying acute bronchitis)

(2)

- Relief of pain and anti-inflammation in the following diseases and symptoms:
  Rheumatoid arthritis, osteoarthritis, low back pain, afterbirth pain
- Relief of pain and anti-inflammation after surgery
- Emergency antipyresis for acute upper respiratory inflammation (including acute upper respiratory inflammation accompanying acute bronchitis) refractory to other antipyretics or other antipyretics cannot be administered

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(3)

Relief of pain and anti-inflammation in the following diseases and symptoms

Rheumatoid arthritis, osteoarthritis, low back pain, periarthritis scapulohumeralis, neck, shoulder and arm syndrome

Summary of revision

"Gastrointestinal stenosis and obstruction" should be newly added in the Clinically significant adverse reaction section.

Background of the revision and investigation results

Cases of gastrointestinal stenosis or obstruction have been reported in patients treated with diclofenac sodium in Japan. In addition, the company core datasheet (CCDS)* has been updated. Following an investigation result based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan

A total of 5 cases associated with gastrointestinal stenosis or obstruction have been reported (including 4 cases for which a causal relationship to the product could not be ruled out; however, 1 case was for a condition not included in the approved dosage and administration). No fatality has been reported.

Note:

*CCDS is prepared by the marketing authorization holder and covers materials relating to safety, indications, dosing, pharmacology, and other information concerning the product.

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