



Selecox[®]

Celecoxib

Analgesic & Anti-inflammatory

COMPOSITION

Selecox[®] 100 : Each capsule contains Celecoxib INN 100 mg.

Selecox[®] 200 : Each capsule contains Celecoxib INN 200 mg.

PHARMACOLOGY

Celecoxib is a nonsteroidal anti-inflammatory drug that exhibits anti-inflammatory, analgesic and antipyretic activities. The mechanism of action of Celecoxib is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2) and at therapeutic concentrations in humans, Celecoxib does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme.

INDICATION

For relief of the signs and symptoms of osteoarthritis.

For relief of the signs and symptoms of rheumatoid arthritis.

For relief of pain after dental extraction.

For reduction of colorectal polyps in Familial Adenomatous Polyposis (FAP).

DOSAGE AND ADMINISTRATION

The lowest dose of Celecoxib should be sought for each patient.

Osteoarthritis: For relief of the signs and symptoms of osteoarthritis, the recommended oral dose is 200 mg of Celecoxib (Selecox[®] 200) per day administered as a single dose or as 100 mg of Celecoxib (Selecox[®] 100) twice daily. *Rheumatoid arthritis:* For relief of the signs and symptoms of rheumatoid arthritis, the recommended oral dose is 100 to 200 mg of Celecoxib twice daily. *Dental pain:* Single dose of Celecoxib 100 mg (one Selecox[®] 100 capsule) or Celecoxib 400 mg (2xSelecox[®] 200 capsules).

FAP: Recommended daily dose is Celecoxib 400 mg (2xSelecox[®] 200 capsules) twice daily.

CONTRAINDICATION AND PRECAUTION

Celecoxib is contraindicated in patients with known hypersensitivity to this drug. It should not be given to patients who have demonstrated allergic type reactions to sulfonamides. Celecoxib should not be given to patients who have experienced asthma, urticaria or allergic-type reactions after taking aspirin or other NSAIDs.

During Celecoxib therapy minor upper gastrointestinal problems, such as dyspepsia, may occur. Anaphylactoid reactions were not reported in patients

NSAID PREPARATIONS

Selecox[®]

receiving Celecoxib in clinical trials. However, as with NSAIDs in general, anaphylactoid reactions may occur in patients without known prior exposure to Celecoxib. It should not be given to patients with the aspirin triad. Caution should be used when initiating treatment with Celecoxib in patients with considerable dehydration. It is advisable to rehydrate patients first and then start therapy with Celecoxib.

SIDE EFFECT

The following adverse effects occurred in 0.1-1.9 % of patients: constipation, dysphagia, eructation, esophagitis, gastritis, gastroesophageal reflux disease, stomatitis, vomiting, dry mouth, glaucoma, allergic reaction, generalized edema, fever, hot flushes, vertigo, photosensitivity reaction, pruritus, dry skin, increased sweating, urticaria.

DRUG INTERACTION

Furosemide: NSAIDs can reduce the matriuretic effect of furosemide and thiazides in some patients. *Fluconazole:* Concomitant administration of fluconazole at 200 mg QD resulted in a two-fold increase in celecoxib plasma concentration. *Warfarin:* Caution should be exercised when administering Celecoxib with warfarin since these patients are at increased risk of bleeding complications.

USE IN PREGNANCY AND LACTATION

There is no study in pregnant women. Celecoxib should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Celecoxib is excreted in the milk of lactating rats at concentrations similar to those in plasma. It is not known whether this drug is excreted in human milk. The safety and efficacy of Celecoxib are yet to be established in paediatric patients.

STORAGE CONDITION

Store at 15°C to 30°C.

HOW SUPPLIED:

Selecox[®] 100 : Each box contains 12 x 4 capsules in blister pack.

Selecox[®] 200 : Each box contains 12 x 4 capsules in blister pack.

