When patients need fast and powerful pain relief, think CELEBREX®[1-7]

CELEBREX
(CELECOXIB CAPSULES)

CELEBREX® provides a fast onset of action for treating[1,2]:

- Acute pain: CELEBREX® acted as early as 22 minutes (median onset is **28 minutes;** range 22-33 minutes)[1*]
- Post-surgical pain: CELEBREX® controlled pain as early as **1 hour** post dose[2†]

TARGETING ACUTE PAIN WITH CELEBREX®

Acute pain
28 minutes

Post-surgical pain
1 hour

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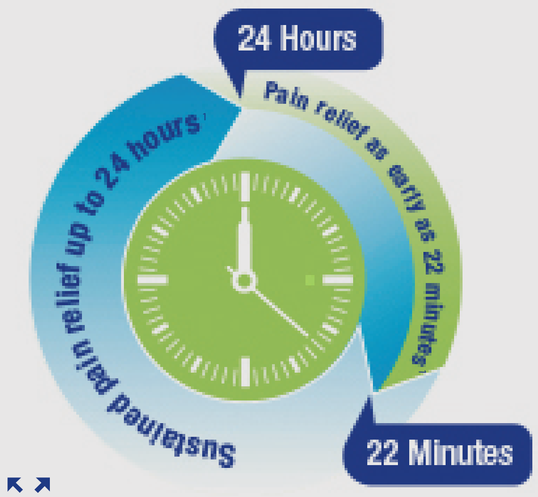
CELEBREX® provides powerful and sustained pain relief[1,3-7]

- Sustained pain relief up to 24 hours[1*]
- Powerful acute pain relief
  - Significant improvement in pain scores[3-6]
  - Rapid return to functioning in patients with ankle sprain[7]
  - Reduction in post-surgical narcotic pill count[5]



*In patients with moderate-to-severe pain following third molar extraction.
†In patients with moderate-to-severe pain after orthopedic surgery.

Please see full product information before prescribing.

References:

1. Cheung R, Krishnaswami S, Kowalski K. Analgesic efficacy of celecoxib in postoperative oral surgery pain: a single-dose, two-center, randomized, double-blind, active- and placebo-controlled study. *Clin Ther*. 2007;29 Suppl:2498-2510.

2. Gimbel JS, Brugger A, Zhao W, Verburg KM, Geis GS. Efficacy and tolerability of celecoxib versus hydrocodone/acetaminophen in the treatment of pain after ambulatory orthopedic surgery in adults. *Clin Ther*. 2001;23(2):228-241.

3. Cardenas-Estrada E, Oliveira LG, Abad HL, Elayan F, Khalifa N, El-Husseini T. Efficacy and safety of celecoxib in the treatment of acute pain due to ankle sprain in a Latin American and Middle Eastern population. *J Int Med Res*. 2009;37(6):1937-1951.

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5. Schroer WC, Diesfeld PJ, LeMarr AR, Reedy ME. Benefits of prolonged postoperative cyclooxygenase-2 inhibitor administration on total knee arthroplasty recovery: a double-blind, placebo-controlled study. *J Arthroplasty.* 2011;26(6 Suppl.1):2-7.

6. White PF, Sacan O, Tufanogullari B, Eng M, Nuangchamnong N, Ogunnaike B. Effect of short-term postoperative celecoxib administration on patient outcome after outpatient laparoscopic surgery. *Can J Anaesth*. 2007;54(5):342-348.

7. Ekman EF, Fiechtner JJ, Levy S, Fort JG. Efficacy of celecoxib versus ibuprofen in the treatment of acute pain: a multicenter, double-blind, randomized controlled trial in acute ankle sprain. *Am J Orthop (Belle Mead NJ)*. 2002;31(8);445-451.

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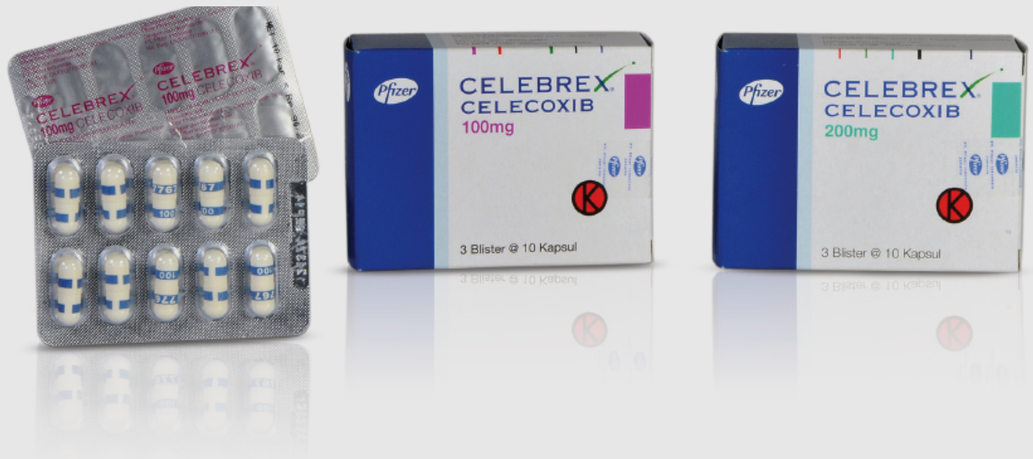
*In pati
†In patients with moderate-to-severe pain after orthopedic surgery.



Abbreviated Product Information: CELEBREX®

DESCRIPTION: CELEBREX® (celecoxib) is chemically designated as 4-[5-(4-methylphenyl)-3-(trifluoromethyl)-1 H-pyrazol-1-yl) benzenesulfonamide and is a diaryl substituted pyrazole. MECHANISM OF ACTION: CELEBREX® is a non-steroidal anti-inflammatory drug that exhibits anti-inflammatory, analgesic, and antipyretic activities in animal models. The mechanism of action of CELEBREX® is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, CELEBREX® does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme. INDICATIONS AND USAGE: Carefully consider the potential benefits and risks of CELEBREX® and other treatment options before deciding to use CELEBREX®. Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals. CELEBREX® is indicated: 1). For relief of the signs and symptoms of osteoarthritis ; 2). For relief of the signs and symptoms of rheumatoid arthritis in adults; 3). For relief of signs and symptoms of ankylosing spondylitis. 4). For the short-treatment of acute pain in adults following surgery or musculoskeletal injury. CONTRAINDICATIONS: CELEBREX® is contraindicated in patients with known hypersensitivity to celecoxib or any other ingredient of the product, patients who have demonstrated allergic-type reactions to sulfonamides and patients who have experienced asthma, urticaria, or allergic-type reactions after taking acetyl salicylic acid or other NSAIDs, including other cyclooxygenase-2 (COX-2) specific inhibitors. Severe, rarely fatal, anaphylactic-like reactions to NSAIDs have been reported. CELEBREX® is contraindicated for the treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery. WARNINGS: Chronic use of CELEBREX® may cause an increased risk of serious adverse cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. All NSAIDs, both COX-2 selective and non-selective, may have a similar risk. Patients with CV disease or CV risk factors may be at greater risk. To minimize the potential risk for an adverse CV event in patients treated with CELEBREX®, the lowest effective dose should be used for the shortest duration possible. As with all NSAIDS, CELEBREX® can lead to the onset of new hypertension or worsening of pre-existing hypertension, either of which may contribute to the increased incidence of CV events. Fluid retention and edema have been observed in some patients taking NSAIDs, Including CELEBREX®. NSAIDs, including CELEBREX®, can cause serious gastrointestinal events including bleeding, inflammation, ulceration, and upper and lower gastrointestinal perforation, small intestine or large intestine, which can be fatal. No information is available regarding the use of CELEBREX® in patients with advanced renal disease. Therefore, treatment with CELEBREX® is not recommended in these patients with advanced renal disease. As with NSAIDs in general, anaphylactoid reactions have occurred in patients without known prior exposure to CELEBREX®. CELEBREX® should not be given to patients with the acetyl salicylic acid triad. CELEBREX® is a sulfonamide and can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TENS), which can be fatal. PRECAUTIONS: A patient with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver test has occurred, should be monitored carefully for evidence of the development of a more severe hepatic reaction while on therapy with CELEBREX®. CELEBREX® should not be administered to patients with this form of acetyl salicylic acid sensitivity and should be used with caution in patients with pre-existing asthma. Fertility: Based on the mechanism of action, the use of NSAIDs, may delay or prevent rupture of ovarian follicles, which has been associated with reversible infertility in some women. In women who have difficulties conceiving or who are undergoing investigation of infertility withdrawal of NSAIDs, including celecoxib, should be considered. Pregnancy: In late pregnancy CELEBREX® should be avoided because it may cause premature closure of the ductus arteriosus. Inhibition of prostaglandin synthesis might adversely affect pregnancy. Data from epidemiological studies suggest an increased risk of spontaneous abortion after use of prostaglandin synthesis inhibitors in early pregnancy. In animals, administration of prostaglandin synthesis inhibitors has been shown to result in increased pre- and post-implantation loss. Nursing mothers: Celecoxib is excreted in the milk of lactating rats at concentrations similar to those in plasma. DRUG INTERACTIONS: CELEBREX® metabolism is predominantly mediated via cytochrome P450 2C9 in the liver. Interaction should be given consideration in patients taking CELEBREX® concomitantly with ACE-inhibitors, furosemide, acetyl salicylic acid, fluconazole, lithium, warfarin. ADVERSE REACTIONS: Dyspepsia, diarrhea, dizziness and sinusitis. DOSAGE AND ADMINISTRATION: Carefully consider the potential benefits and risks of CELEBREX® and other treatment options before deciding to use CELEBREX®. Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals. For osteoarthritis and rheumatoid arthritis, the lowest dose of CELEBREX® should be sought for each patient. These doses can be given without regard to timing of meals. Osteoarthritis: For relief of the signs and symptoms of Osteoarthritis the recommended oral dose is 200 mg per day administered as a single dose or as 100 mg twice per day. Rheumatoid arthritis: For relief of the signs and symptoms of rheumatoid arthritis the recommended oral dose is 100 to 200 mg twice per day. Ankylosing Spondylitis: The recommended dose of celecoxib is 200 mg administered as a single dose or as 100 mg twice per day. Some patients may benefit from a total daily dose of 400 mg. Management of Acute Pain: The recommended dose is 400 mg, initially, followed by an additional 200 mg dose, if needed on the first day. On subsequent days, the recommended dose is 200 mg twice daily maximum 7 days. For patient with Hepatic insufficiency: The daily recommended dose of CELEBREX® capsules in patients with moderate hepatic impairment (Child-Pugh Class B) should be reduced by approximately 50%. The use of CELEBREX® in patients with severe hepatic impairment is not recommended. CYP2C9 Poor Metabolizers: Patients who are known, or suspected to be CYP2C9 poor metabolizers based on previous history/experience with other CYP2C9 substrates should be administered celecoxib with caution. Consider starting treatment at half the lowest recommended dose. Renal Impairment: There is no clinical experience in patients with severe renal impairment. Supply: CELEBREX® 100 mg; box of 3 blisters @ 10 capsules; Reg. No.: DKI1465700201A1. CELEBREX® 200 mg; box of 3 blisters @ 10 capsules; Reg. No.: DKI1465700201B1. Special Precautions for Storage: Store below 25ºC. HARUS DENGAN RESEP DOKTER.

Reference: Latest BPOM Approved Celebrex Local Product Document. 2018.

Working together for a healthier world™

Full product information can be requested to
PT. Pfizer Indonesia
Wisma GKBI lt. 10
Jl. Jend. Sudirman No. 28, Jakarta 10210

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