AS, ankylosing spondylitis; OA, osteoarthritis; RA, rheumatoid arthritis

References. 1. Celebrex product information (100mg, 200mg, 400mg revision date 2022.04.08) **2.** Ministry of Health and Welfare Notification No. 2017-215.

[Summary of Celebrex Safety Information] Gastrointestinal risk: Low-dose 325mg a day combined administration of aspirin is possible, but an increase in gastrointestinal adverse events has been reported compared to single administration. Cardiovascular Risk: This drug may increase the risk of serious cardiovascular thrombotic reactions, myocardial infarction, and stroke, which can be fatal.

[Summarized product information] [COMPOSITION] 1) Celebrex Capsule 100 mg: 1 capsule contains Celecoxib (USP) 100 mg. Inactive ingredient (Tar color): FD&C Blue #2. Other inactive ingredients: Hard gelatin capsule shell, sodium lauryl sulfate, magnesium stearate, lactose, purified water, croscarmellose sodium, povidone. 2) Celebrex Capsule 200 mg: 1 capsule contains Celecoxib (USP) 200 mg. Inactive ingredients: Sodium lauryl sulfate, magnesium stearate, lactose monohydrate, purified water, capsule shell, croscarmellose sodium, povidone. 3) Celebrex Capsule 400 mg: 1 capsule contains 400 mg of celecoxib (USP). Inactive ingredient (Tar color): FD&C Blue #1. Other inactive ingredients: Hard gelatin capsule, sodium lauryl sulfate, magnesium stearate, lactose monohydrate, croscarmellose sodium, povidone. [APPEARANCE] 1) Celebrex Capsule 100 mg: White capsules with blue ink band on the body and cap filled with white or off-white powder. 2) Celebrex Capsule 200 mg: White capsules with gold ink band on the body and cap filled with white or off-white powder. 3) Celebrex Capsule 400 mg: White capsules with green ink band on the body and cap filled with white or off-white powder. [INDICATIONS] 1) 100 mg, 200 mg: 1. For relief of the signs and symptoms of osteoarthritis (degenerative osteoarthritis [OA]). 2. For relief of the signs and symptoms of rheumatoid arthritis (RA) in adults. 3. For the relief of signs and symptoms of ankylosing spondylitis (AS). 4. For the management of acute pain in adults (post-oral surgery pain, post-orthopedic surgical pain). 5. Primary dysmenorrhea. 2) 400 mg: 1. For the relief of signs and symptoms of ankylosing spondylitis. 2. For the management of acute pain in adults (post-oral surgery pain, post-orthopedic surgical pain). 3. Primary dysmenorrhea. [DOSAGE AND ADMINISTRATION] 1) 100 mg, 200 mg: 1. Osteoarthritis (Degenerative Osteoarthritis): the recommended oral dose is 200 mg/day administered as a single dose or as 100 mg twice per day. 2. Rheumatoid arthritis (RA): the recommended oral dose of Celebrex is 100 mg to 200 mg twice per day. 3. Ankylosing Spondylitis (AS): the recommended dose of Celebrex is 200 mg daily single (once per day) or divided (twice per day) doses. If no effect is observed after 6 weeks, a trial of 400 mg daily may be worthwhile. If no effect is observed after 6 weeks, a response is not likely and consideration should be given to alternate treatment options. 4. Acute Pain and Primary Dysmenorrhea: The recommended dose of Celebrex 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 as needed. 5. Patient with hepatic impairment: The dosage for patients with moderate hepatic impairment (Child–Pugh Class II) should be reduced by approximately 50% of the daily recommended dose. 2) 400 mg: The lowest dose of Celebrex should be sought for each patient. These doses can be given without regard to timing of meals. 1. Ankylosing Spondylitis (AS): the recommended dose of Celebrex is 200 mg daily single (once per day) or divided (twice per day) doses. If no effect is observed after 6 weeks, a trial of 400 mg daily may be worthwhile. If no effect is observed after 6 weeks on 400 mg daily, a response is not likely and consideration should be given to alternate treatment options. 2. Acute Pain and Primary Dysmenorrhea: The recommended dose of Celebrex 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 as needed. 3. Patient with hepatic impairment: The dosage for patients with moderate hepatic impairment (Child–Pugh Class II) should be reduced by approximately 50% of the daily recommended dose. [WARNING] 1) If you consume 3 or more alcoholic drinks every day, ask your doctor or pharmacist whether you should take celecoxib or other pain relievers or fever reducers. It can cause gastrointestinal (GI) bleeding. 2) Cardiovascular Thrombotic Events: Celecoxib may cause an increased risk of serious cardiovascular (CV) thrombotic events, myocardial infarction (MI), and stroke, which can be fatal. All NSAIDs may have a similar risk. This risk may increase with dose and duration of use. In terms of serious cardiovascular thrombotic events by NSAIDs, the relative increase from baseline appears to be similar in those with or without known CV disease or CV risk factors. However, absolute incidence appears to be increased due to increased cardiovascular thrombotic event rate at baseline. To minimize the potential risk for an adverse CV event in patients treated with celecoxib, the lowest effective dose should be used for the shortest duration possible. Physicians and patients should remain alert for the development of such events, even in the absence of previous CV symptoms. Patients should be informed about the signs and symptoms of serious CV toxicity (chest pain, shortness of breath, weakness, slurring of speech) and the steps to take if they occur. 3) Gastrointestinal (GI) Risk: Upper and lower GI perforations, ulcers or bleeds have occurred in patients treated with celecoxib, NSAIDs, including Celebrex, cause an increased risk of serious GI adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious GI events. With longer duration of use of NSAIDs, there is a trend for increasing the likelihood of developing a serious GI event at some time during the course of therapy. However, even short-term therapy is not without risk. Physicians and patients should remain alert for signs and symptoms of GI ulceration and bleeding during Celebrex therapy and promptly initiate additional evaluation and treatment if any signs or symptoms that are indicative of these disorders including epigastric pain, dyspepsia, melena, hematemesis, or a serious GI adverse event are suspected. For high-risk patients, alternate therapies that do not involve NSAIDs should be considered. [CONTRAINDICATIONS] Patients with known hypersensitivity to celecoxib or any other ingredient of the product. Patients who have demonstrated allergic-type reactions to sulfonamides. Patients who have experienced asthma, acute rhinitis, nasal polyps, angioedema, urticaria, or allergic-type reactions after taking aspirin or other NSAIDs, including cyclooxygenase-2 (COX-2) inhibitors. Patients with severe hepatic insufficiency. Patients with severe renal insufficiency (patients with estimated creatinine clearance <30 mL/min). Patients with active peptic ulceration or GI bleeding. Patients with inflammatory bowel disease such as Crohn's disease or ulcerative colitis. Patients with congestive heart failure (NYHA II-IV). Patients with established ischaemic heart disease, peripheral arterial disease and/or cerebrovascular disease. In pregnancy and in women of childbearing potential. Breast feeding. Treatment of peri-operative pain in the setting of coronary artery bypass graft (CABG) surgery. Patients with hyperkalaemia. This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp-lactase deficiency or glucose-galactose malabsorption should not take this medicine. [ADMINISTRATIONS WITH CAUTION] Patients with hepatic insufficiency or prior history. Patients with renal insufficiency or prior history (Creatinine clearance <60 mL/min). Patients with bronchial asthma. Patients with heart failure or prior history. Patients with hypertension or prior history. Patients with body fluid retention or prior history of oedema. Patients who are taking diuretics or ACE inhibitors. Patients with the risk of hypovolaemia. Patients with dehydration. The elderly. Patients with a prior history of ulcer disease or GI bleeding. Patients with significant risk factors for CV events (cardiac crisis, stroke) (e.g., hypertension, hyperlipidaemia, diabetes mellitus, smoking), patients with CV disease or a prior history of CV disease. Patients who are known or suspected to be CYP2C9 poor metabolizer. Patients with blood coagulation disorder or patients on concurrent therapy with anticoagulant. Female with plan of pregnancy. Patients with diabetes mellitus. [ADVERSE REACTIONS] 1) Clinical Trials Experience (1) Adverse Drug Reactions (ADRs) in 12 placebo- and/or active-controlled clinical trials and ADR frequency from 89 Pain and Inflammation Randomized, Controlled Clinical Trials with Daily Doses of 25 mg – 800 mg, in adult. Common Adverse Reactions: Bronchitis, sinusitis, upper respiratory tract infection, urinary tract infection, insomnia, dizziness, hypertension (including aggravated hypertension), cough, vomiting, abdominal pain, diarrhea, dyspepsia, flatulence, pruritus (includes pruritus generalized), rash, oedema peripheral. (2) In comparative clinical trials, the discontinuation rate due to adverse events was 7.1% for patients receiving Celebrex and 6.1% for patients receiving placebo. Among the most common reasons for discontinuation due to adverse events in the Celebrex treatment groups were dyspepsia and abdominal pain. [GENERAL PRECAUTIONS] Celecoxib is not a substitute for acetylsalicylic acid for prophylaxis of CV thromboembolic diseases because of the lack of effect on platelet function. Because celecoxib does not inhibit platelet aggregation, anti-platelet therapies (e.g., acetylsalicylic acid) should not be discontinued. [INTERACTIONS] Celecoxib metabolism is predominantly mediated via CYP2C9 in the liver. Co-administration of celecoxib with drugs that are known to inhibit CYP2C9 should be done with caution. There is no consistent evidence that concurrent use of aspirin mitigates the increased risk of serious CV thrombotic events associated with NSAID use. Celebrex can be used with low dose aspirin (≤ 325 mg/day). However, it has been reported that concomitant administration of aspirin with Celebrex increase rate of GI events (GI ulceration) or other GI complications, compared to use of Celebrex alone. [USE IN PREGNANCY AND LACTATION] If used during second or third trimester of pregnancy, NSAIDs may cause fetal renal dysfunction which may result in reduction of amniotic fluid volume or oligohydramnios in severe cases. Such effects may occur shortly after treatment initiation and are usually reversible upon discontinuation. Pregnant women on celecoxib should be closely monitored for amniotic fluid volume. [PACKAGE UNIT] 1) 100 mg, 200 mg: 30 Capsules/Blister, 100 Capsules/Bottle. 2) 400 mg: 30 Capsules/Blister. * For the lately revised product information, please visit www.pfizer.co.kr. For further information about the product, please refer to the product information. Latest HA approved date: 08 Apr 2022.

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