Celecoxib

Coxid® 200 mg Capsule & 400 mg Capsule

Selective Cyclooxygenase (COX)-2 Inhibitor

℞

FORMULATION

Each capsule contains:

Celecoxib …… 200 or 400 mg

PRODUCT DESCRIPTIONS

Celecoxib (Coxid®) 200 mg Capsule is a size "1" hard-gelatin capsule with a violet cap and white body containing a white to off-white powder.

Celecoxib (Coxid®) 400 mg Capsule is a size "00" hard-gelatin capsule with a dark yellow cap and white body containing a white to off-white powder.

CLINICAL PHARMACOLOGY

Pharmacodynamics

Celecoxib exhibits anti-inflammatory, analgesic, and antipyretic activities by selectively inhibiting cyclooxygenase-2 (COX-2) isoenzymes resulting in inhibition of prostaglandin synthesis. Traditional non-steroidal anti-inflammatory drugs (NSAIDs) appear to inhibit prostaglandin synthesis through inhibition of both COX-1 and COX-2 isoenzymes.

At therapeutic doses, celecoxib does not inhibit COX-1 isoenzyme, thus, it does not interfere with the normal COX-1 related physiological processes in tissues, such as the stomach, intestine and platelets.

Pharmacokinetics

Celecoxib is well absorbed from the GI tract. Peak plasma levels occur approximately 2 to 3 hours after the drug is given orally under fasting conditions. After oral administration of a single 200 mg dose of celecoxib in healthy fasting adults, peak plasma concentrations (C_{max}) of the drug averaged 705 ng/mL. When celecoxib was taken with a high fat meal (24 g fat), bioavailability (AUC) was increased by 10 to 20% and time to reach peak plasma levels (T_{max}) was delayed by 1 to 2 hours compared with administration with a medium-fat meal (8 g fat) or under fasting conditions. The AUC and plasma concentration 12 hours after a celecoxib dose were slightly higher when the drug was given in the evening versus in the morning. Under fasting conditions, at doses above 200 mg, there is less than a proportional increase in Cmax and AUC, which is thought to be due to the low solubility of the drug in aqueous media. After oral administration of celecoxib at recommended doses of 200 to 400 mg/day, steady-state plasma concentrations are reached within five days. Celecoxib doses up to 200 mg twice a day can be administered without regard to timing of meals. Higher doses (400 mg twice a day) should be given with food to improve absorption.

Celecoxib's protein binding is 97%. The apparent volume of distribution at steady state is about 400 L (about 7.14 L/kg), suggestive of extensive tissue distribution. Celecoxib is not bound to erythrocytes. It is not known whether celecoxib crosses human placenta.

Celecoxib is extensively metabolized in the liver; metabolism is primarily mediated via cytochrome P450 2C9. Three metabolites have been identified in human plasma: a primary alcohol, the corresponding carboxylic acid and its glucuronide conjugate. Celecoxib's metabolites do not have pharmacologic activity as COX-1 and 2 inhibitors. (see Drug Interactions)

Celecoxib is excreted in urine and feces principally as metabolites; less than 3% of the dose is excreted unchanged. Under fasted condition, the effective half-life is approximately 11 hours. The apparent plasma clearance (CL/F) is about 500 mL/min.

Special Populations:

Hepatic Impairment: In patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment, the AUC of celecoxib at steady state was increased about 40 or 180%, respectively, above that seen in healthy subjects.

Renal Impairment: In patients with chronic renal insufficiency (glomerular filtration rates of 35 to 60 mL/minute), the AUC of celecoxib was 40% lower than in adults with normal renal function.

Geriatric: In geriatric patients above 65 years old, peak plasma concentration and AUC were increased 40 and 50%, respectively, compared with younger adults.

INDICATIONS

- Relief of the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis
- Relief of the signs and symptoms of juvenile rheumatoid arthritis (JRA) in patients 2 years and older
- Management of acute pain, including postoperative dental or orthopedic pain, and treatment of primary dysmenorrhea

Carefully consider the potential benefits and risks of celecoxib and other treatment options before deciding to use celecoxib.

DOSAGE AND ADMINISTRATION

Celecoxib dosages up to 200 mg twice a day may be taken with or without food; higher doses, i.e., 400 mg twice a day, should be given with food to improve absorption.

As with other NSAIDs, the lowest effective dose of celecoxib should be used for the shortest possible time.

INDICATION	USUAL ORAL ADULT DOSE
Osteoarthritis	**200 mg once a day**
Rheumatoid Arthritis	**100 mg to 200 mg twice a day**
Ankylosing spondylitis	**200 mg once a day** If no response is observed after 6 weeks, the dose may be increased to 400 mg once a day. If no response is observed on 400 mg/day for 6 weeks, response is unlikely and alternative treatment options should be considered.
Acute Pain and Primary Dysmenorrhea	**400 mg initially followed by an additional dose of 200 mg, if needed, on the first day** On subsequent days, 200 mg twice a day may be given, as needed.
Or, as prescribed by a physician.	

INDICATION	USUAL ORAL PEDIATRIC DOSE
Juvenile Rheumatoid Arthritis	To be administered to children 2 years and older. **Dose for 10 to 25 kg Body Weight: 50 mg twice a day** **Dose for >25 kg Body Weight: 100 mg twice a day** For children who have difficulty swallowing capsules, the contents of the celecoxib capsule may be added to applesauce. The contents of the entire capsule should be carefully emptied onto a level teaspoon of cool or room temperature applesauce and ingested immediately with water.
Or, as prescribed by a physician.	

Special Populations:

Hepatic Impairment: The daily dose of celecoxib should be reduced by approximately 50% in patients with moderate hepatic impairment. The use of celecoxib in patients with severe hepatic impairment is not recommended.

Renal Insufficiency: There is no clinical experience in patients with severe renal impairment thus the use of celecoxib is not advised.

Poor Metabolizers of CYP2C9 Substrates: Celecoxib should be administered with caution in patients who are poor CYP2C9 metabolizers based on genotype or previous history with other CYP2C9 substrates such as warfarin or phenytoin. Consider starting treatment at half of the lowest recommended dose in poor metabolizers and consider using alternative management in JRA patients who are poor metabolizers.

CONTRAINDICATIONS

Absolute Contraindications

Not to be given to those patients who have history of:

- Stroke: cerebrovascular accident, CVA
- Heart attack: Myocardial infarction, MI
- Coronary artery bypass graft: CABG
- Uncontrolled hypertension
- Congestive heart failure (CHF) NYHA II-IV

- Hypersensitivity to celecoxib, aspirin and other NSAIDs, or to any ingredient in the product
- Patients with allergic-type reactions to sulfonamides
- Patients who have experienced asthma, urticaria or allergic-type reactions after taking aspirin or other NSAIDs, including other COX-2 specific inhibitors. Severe, rarely fatal, anaphylactoid reactions to NSAIDs have been reported in such patients.
- Patients with previous or active peptic ulceration or gastrointestinal bleeding, or inflammatory bowel disease
- Patients with unstable or significant established ischaemic heart disease, peripheral arterial disease and/or cerebrovascular disease
- Patients with advanced renal or hepatic disease.

WARNINGS and PRECAUTIONS

Cardiovascular Risk

- Celecoxib may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. All nonsteroidal anti-inflammatory drugs (NSAIDs) may have a similar risk. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.

Gastrointestinal Risk

- NSAIDs, including Celecoxib, cause an increased risk of serious gastrointestinal 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 gastrointestinal events.

Celecoxib should be used with caution in patients with cardiac, hepatic or renal disease.
Patients should be carefully monitored while receiving treatment with Celecoxib.
The lowest effective dose of Celecoxib should be used for the shortest possible time.

Cardiovascular Effects

Cardiovascular Thrombotic Events

Clinical trials using COX-2 selective and nonselective NSAIDs of up to three years duration have shown an increased risk of serious cardiovascular (CV) thrombotic events, myocardial infarction and stroke, which can be fatal. Patients with known CV disease or risk factors for CV disease may be at greater risk. To minimize the potential risk for an adverse CV event in patients treated with an NSAID, the lowest effective dose should be used for the shortest duration possible. Physicians and patients should be alert to the development of such events, even in the absence of previous CV symptoms. Patients should be informed on the signs and/or symptoms of serious CV events and the steps to take if they occur.

There is no consistent evidence that concurrent use of aspirin mitigates the increased risk of serious CV thrombotic events associated with NSAID use. The concurrent use of aspirin and an NSAID does increase the risk of serious GI events.

Two large, controlled, clinical trials of a different COX-2 selective NSAID for the treatment of pain found an increased incidence of myocardial infarction and stroke in the first 10 to 14 days following CABG surgery.

Hypertension

NSAIDs, including celecoxib, can lead to the onset of new hypertension or worsening of preexisting hypertension, either of which may contribute to the increased incidence of CV events. Patients taking thiazides or loop diuretics may have impaired response to these therapies when taking NSAIDs. NSAIDs, including celecoxib, should be used with caution in patients with hypertension. Blood pressure should be monitored closely during initiation of NSAID treatment and throughout the course of therapy.

Congestive Heart Failure and Edema

Fluid retention and edema have been observed in some patients taking NSAIDs, including celecoxib. Celecoxib should be used with caution in patients with fluid retention or heart failure.

Gastrointestinal Effects

NSAIDs, including celecoxib, can cause serious gastrointestinal (GI) adverse events including inflammation, bleeding, ulceration, and perforation of the stomach, small or large intestines, which can be fatal. These serious adverse events can occur at any time, with or without warning symptoms, in patients treated with NSAIDs.

NSAIDs should be prescribed with extreme caution in those with a history of ulcer disease or gastrointestinal bleeding since these patients have a greater than 10-fold increased risk for developing a GI bleed compared with patients with neither of these risk factors. Other factors that increase the risk for GI bleeding in patients treated with NSAIDs include concomitant use of oral corticosteroids or anticoagulants, longer duration of NSAID therapy, smoking, use of alcohol, older age, and poor general health status. Elderly patients, in particular, are at greater risk for serious gastrointestinal events.

The lowest effective dose should be used for the shortest possible duration to minimize the potential risk for an adverse GI event. Physicians and patients should remain alert for signs and symptoms of GI ulceration and bleeding during NSAID therapy and promptly initiate additional evaluation and treatment if a serious GI adverse event is suspected. This should include discontinuation of the NSAID until a serious GI adverse event is ruled out. Alternate therapies that do not involve NSAIDs should be considered especially for high-risk patients.

Renal Effects

Long-term administration of NSAIDs has resulted in renal papillary necrosis and other renal injury. Renal toxicity has also been seen in patients in whom renal prostaglandins have a compensatory role in the maintenance of renal perfusion. In these patients, administration of an NSAID may cause a dose-dependent reduction in prostaglandin formation and secondarily, in renal blood flow, which may precipitate overt renal decompensation. Patients at greatest risk of this reaction are those with impaired renal function, hypovolemia, heart failure, liver dysfunction, salt depletion, those taking diuretics and Angiotensin Converting Enzyme (ACE) inhibitors, and the elderly. Discontinuation of NSAID therapy is usually followed by recovery to the pretreatment state.

Advanced Renal Disease

There are no controlled studies on the use of celecoxib in patients with advanced renal disease. Therefore, treatment with celecoxib is not recommended in these patients. If celecoxib therapy must be initiated, close monitoring of the patient's renal function is advisable.

Anaphylactoid Reactions (see Contraindications)

Anaphylactoid reactions may occur in patients without known prior exposure to NSAIDs. Celecoxib should not be given to patients with the aspirin triad. This symptom complex typically occurs in asthmatic patients who experience rhinitis with or without nasal polyps, or who exhibit severe, potentially fatal bronchospasm after taking aspirin or other NSAIDs. Celecoxib should be administered with caution to patients with preexisting asthma and emergency help should be sought in cases where an anaphylactoid reaction occurs.

Skin Reactions

Celecoxib can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. These serious events may occur without warning. Patients should be informed about the signs and symptoms of serious skin manifestations and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

Hepatic Effects

Borderline elevations of one or more liver tests may occur in up to 15% of patients taking NSAIDs, including celecoxib. These laboratory abnormalities may progress, may remain unchanged or may be transient with continuing therapy. Notable elevations of alanine aminotransferase (ALT) or aspartate aminotransferase (AST) (approximately three or more times the upper limit of normal) have been reported in approximately 1% of patients in clinical trials with NSAIDs. Rare cases of severe hepatic reactions, including jaundice and fatal fulminant hepatitis, liver necrosis, and hepatic failure, some with fatal outcomes have been reported.

Patients with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver test has occurred, should be evaluated for evidence of the development of a more severe hepatic reaction while on therapy with NSAIDs. Discontinue celecoxib if clinical signs and symptoms consistent with liver disease develop or if systemic manifestations occur (e.g., eosinophilia, rash).

Hematologic Effects

Anemia is sometimes seen in patients receiving NSAIDs including celecoxib. Patients on long-term treatment with NSAIDs, including celecoxib, should have their hemoglobin or hematocrit checked if they exhibit any signs or symptoms of anemia or blood loss. Celecoxib does not generally affect platelet counts, prothrombin time (PT), or partial thromboplastin time (PTT), and does not inhibit platelet aggregation at indicated dosages.

Corticosteroid Treatment

Caution should be exercised when using corticosteroids during celecoxib therapy because of the increased risk of GI ulceration. Celecoxib is not a substitute for corticosteroid therapy and the drug is not effective in the management of corticosteroid insufficiency. Abrupt discontinuation of corticosteroids may exacerbate corticosteroid-responsive conditions, thus, patients on prolonged corticosteroid therapy should have their therapy tapered slowly if a decision is made to discontinue corticosteroids.

Disseminated Intravascular Coagulation (DIC)

The use of NSAIDs, such as celecoxib, has been associated with modest prolongation of activated partial thromboplastin time (aPTT) in children with systemic onset JRA. Celecoxib should be used with caution in these children due to the risk of disseminated intravascular coagulation. Children with systemic onset JRA who are receiving celecoxib should be monitored with coagulation tests.

Inflammation

Celecoxib's ability to reduce inflammation, and possibly fever, may diminish the utility of these diagnostic signs in detecting infectious complications of presumed noninfectious, painful conditions.

INTERACTIONS WITH OTHER MEDICAMENTS

General: Celecoxib metabolism is predominantly mediated via cytochrome P450 (CYP) 2C9 in the liver. Co-administration of celecoxib with drugs that are known to inhibit CYP2C9 (e.g., fluconazole, fluvastatin, zafirlukast) should be done with caution. Significant interactions may occur when celecoxib is administered together with drugs that inhibit CYP2C9.

In vitro studies indicate that celecoxib, although not a substrate, is an inhibitor of CYP2D6. Therefore, there is a potential for an *in vitro* drug interaction with drugs that are metabolized by CYP2D6 (e.g., phenytoin, fluvastatin, warfarin, ibuprofen, naproxen).

Specific Drug Interactions:

CONCOMITANT DRUG	EFFECTS
Angiotensin-converting enzyme (ACE) inhibitors, angiotensin II receptor "antagonist"	NSAIDs may diminish the antihypertensive effect of ACE inhibitors and angiotensin II antagonists. There is some evidence that concomitant administration of celecoxib may reduce the blood pressure response to ACE inhibitors and angiotensin II receptor antagonists, thus, blood pressure response should be monitored carefully.
Antacids	Concomitant administration of celecoxib with an aluminum- or magnesium-containing antacid decreased celecoxib's peak plasma concentrations by 37% and AUC by 10%. However, these effects are not considered clinically important.
Aspirin, other NSAIDs (e.g. ibuprofen, mefenamic acid, naproxen sodium)	Celecoxib can be used with low dose aspirin, however, concomitant use of celecoxib with aspirin and other NSAIDs may result in an increased rate of GI ulceration or other complications, compared with the use of celecoxib alone. Celecoxib is not a substitute for aspirin for cardiovascular prophylaxis because of its lack of platelet effects.
Fluconazole	Concomitant administration of fluconazole 200 mg once a day resulted in a two-fold increase in celecoxib plasma concentration. This increase is due to inhibition of celecoxib metabolism via P450 2C9 by fluconazole. Celecoxib should be given at the lowest recommended dose in patients receiving fluconazole.
Furosemide	NSAIDs can reduce the natriuretic effect of furosemide and thiazides in some patients which may be caused by inhibition of renal prostaglandin synthesis.
Lithium	Celecoxib may decrease the renal clearance of lithium which may lead to increased serum or plasma lithium concentrations. Mean steady-state lithium plasma levels have been reported to increase approximately 17% in subjects receiving lithium 450 mg twice a day with celecoxib 200 mg twice a day. Patients on lithium therapy should be closely monitored when celecoxib is introduced or withdrawn.
Methotrexate, Ketoconazole, Phenytoin	Concomitant celecoxib administration did not have a significant effect on the pharmacokinetics and/or pharmacodynamics of methotrexate, ketoconazole and phenytoin. No clinically important interactions have been found.
Oral hypoglycemics (e.g. glibenclamide, tolbutamide)	Concomitant celecoxib administration did not have a significant effect on the pharmacokinetics and/or pharmacodynamics of glibenclamide and tolbutamide, and no clinically important interactions have been found.
Warfarin	Bleeding complications associated with increases in prothrombin time (PT) were reported in some (mainly geriatric) patients receiving celecoxib concomitantly with warfarin. Thus, these patients should be monitored for changes in anticoagulant activity (i.e., PT), particularly in the first few days after initiating or altering therapy, since they may be at an increased risk of bleeding complications.

STATEMENT OF USAGE FOR HIGH-RISK GROUPS

PREGNANCY AND LACTATION

Pregnancy

Pregnancy Category C. Pregnancy Category D from 30 weeks gestation onward. There are no adequate and controlled studies of celecoxib use in pregnant women or during labor and delivery. The drug should be used during pregnancy only when the potential benefits justify the possible risks to the fetus. Celecoxib should not be used during the third trimester of pregnancy since inhibitors of prostaglandin synthesis may have adverse effects on the fetal cardiovascular system (e.g., premature closure of the ductus arteriosus).

Lactation

Caution should be exercised when celecoxib is administered to breastfeeding women. Limited data from 3 published reports of 12 breastfeeding women showed low levels of celecoxib in breast milk. The calculated average daily infant dose was 10 to 40 mcg/kg/day, less than 1% of the weight-based therapeutic dose for a 2 year old child. A report of 2 breastfed infants, 17 to 22 months of age, did not show any adverse events.

USE IN CHILDREN

Celecoxib is approved for the relief of the signs and symptoms of juvenile rheumatoid arthritis (JRA) in patients 2 years old and older. The safety and efficacy of celecoxib therapy beyond 6 months in children with JRA have not been established. The long-term cardiovascular toxicity in children exposed to celecoxib have not been evaluated and it is unknown if long-term risks may be similar to that seen in adults exposed to celecoxib or other COX-2 selective and non-selective NSAIDs.

Celecoxib has not been studied in pediatric patients younger than 2 years old, those weighing less than 10 kg and children with active systemic disease.

USE IN THE ELDERLY

No dosage adjustment is necessary. However, in elderly patients with a lower than average body weight (<50 kg), it is advisable to initiate therapy at the lowest recommended dose.

UNDESIRABLE EFFECTS

At usual dosages, celecoxib is generally well tolerated. Adverse effects are usually mild and mainly involve the GI tract.

Cardiovascular: peripheral edema, angina pectoris, chest pain, coronary artery disorder, myocardial infarction, palpitation, tachycardia, aggravated hypertension, syncope, congestive heart failure, ventricular fibrillation, pulmonary embolism, cerebrovascular accident, peripheral gangrene, thrombophlebitis, deep-vein thrombosis, vasculitis

Gastrointestinal: dyspepsia, diarrhea, constipation, abdominal pain, nausea, vomiting, flatulence, anorexia, diverticulitis, dry mouth, dysphagia, eructation, esophagitis, gastritis, gastroenteritis, gastroesophageal reflux, hemorrhoids, hiatal hernia, increased appetite, melena, stomatitis, taste perversion, tenesmus, tooth disorder, dry socket, intestinal obstruction, intestinal perforation, GI bleeding, colitis with bleeding, esophageal perforation, pancreatitis, cholelithiasis, ileus, intestinal anastomotic ulceration

Nervous System: headache, migraine, dizziness, insomnia, somnolence, anxiety, asthenia, depression, hypertonia, hypoesthesia, nervousness, neuralgia, neuropathy, paresthesia, vertigo, aseptic meningitis, ataxia, ageusia, anosmia, fatal intracranial hemorrhage, suicide

Respiratory: upper respiratory tract infection, sinusitis, pharyngitis, rhinitis, bronchitis, bronchospasm (including aggravated bronchospasm), coughing, dyspnea, laryngitis, pneumonia, nasopharyngitis

Dermatologic and Sensitivity Reactions: rash, alopecia, dermatitis, dry skin, erythematous rash, maculopapular rash, nail disorder, photosensitivity reaction, pruritus, skin disorder, increased sweating, urticaria,

Allergic Reactions: aggravated allergy, bronchospasm, generalized or facial edema, angioedema, anaphylactoid reactions, erythema multiforme, exfoliative dermatitis, Sweet's syndrome, Stevens-Johnson Syndrome, toxic epidermal necrolysis

Hematologic: anemia, ecchymosis, epistaxis, thrombocythemia, agranulocytosis, aplastic anemia, pancytopenia, leukopenia, thrombocytopenia

Renal and Genitourinary: albuminuria, cystitis, dysuria, hematuria, frequent micturition, renal calculus, urinary incontinence, urinary tract infection, dysmenorrhea, genital moniliasis, menstrual disorder, vaginal hemorrhage, vaginitis, prostatic disorder, acute renal failure, interstitial nephritis, renal papillary necrosis, renal injury

Hepatic: Borderline elevations in serum ALT (SGPT) or AST (SGOT), jaundice, hepatitis, fatal fulminant hepatitis, liver necrosis, liver failure

Musculoskeletal: back pain, arthralgia, arthrosis, bone disorder, leg cramps, myalgia, neck stiffness, synovitis, tendinitis, accidental fracture

Special Senses: blurred vision, cataract, conjunctivitis, ocular pain, glaucoma, deafness, ear abnormality, earache, otitis media, tinnitus

Metabolic: increases in: blood urea nitrogen (BUN), creatinine phosphokinase (CPK), nonprotein nitrogen (NPN), creatinine, alkaline phosphatase; diabetes mellitus, hyperglycemia, hypoglycemia, hypercholesterolemia, hypokalemia, hyponatremia, weight gain

General: hot flushes, influenza-like symptoms, accidental injury, cysts, fatigue, fever, flu-like symptoms, soft tissue infection, bacterial infections, fungal infections (including moniliasis), viral infections (including herpes simplex or herpes zoster), pain and peripheral pain, sepsis, sudden death

OVERDOSAGE AND TREATMENT

There is limited experience with celecoxib overdose. Doses of up to 2,400 mg/day for up to 10 days in 12 patients did not result in serious toxicity.

Symptoms following acute NSAID overdosage are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain. These symptoms are usually reversible with supportive care. Gastrointestinal bleeding may occur. Hypertension, acute renal failure, respiratory depression, and coma may rarely occur. Anaphylactoid reactions have been reported with therapeutic ingestion of NSAIDs, and may occur following an overdose.

There is no specific antidote for NSAID overdosage. Treatment of NSAID overdosage involves symptomatic and supportive care. During the first 4 hours after overdosage, emesis and/or administration of activated charcoal (60 to 100 g in adults; 1 to 2 g/kg in children) and/or an osmotic cathartic may be useful in symptomatic patients or in those who reportedly ingested large amounts. It is not known if celecoxib is removed by hemodialysis, but the drug's extensive protein binding (>97%) suggests that forced diuresis, alkalinization of urine, hemodialysis or hemoperfusion is likely to be ineffective in removing substantial amounts of celecoxib from the body.

STORAGE CONDITION

Keep the product out of sight and reach of children.
Store at temperatures not exceeding 30°C. Protect from light.

AVAILABILITY

Celecoxib (Coxid®) 200 mg capsule in Alu-alu blister pack by 10s (box of 30 capsules).
Celecoxib (Coxid®) 400 mg capsule in Alu-alu blister pack by 10s (box of 30 capsules).

CAUTION

Foods, Drugs, Devices, and Cosmetics Act prohibits dispensing without prescription.

DATE OF REVISION: July 2017

ADVERSE DRUG REACTION REPORTING STATEMENT

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph **AND** Unilab at (+632) 858-1000 or productsafety@unilab.com.ph.
By reporting undesirable effects, you can help provide more information on the safety of this medicine.

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