SUMMARY OF PRODUCT CHARACTERISTICS
CELONAL 200 (Celecoxib Capsules 200 mg)

1. NAME OF THE MEDICINAL PRODUCT

CELONAL 200 (Celecoxib Capsules 200 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard gelatin capsule contains 200 mg celecoxib BP.

Excipients with known effect:

Each hard gelatin capsule contains 120 mg of lactose monohydrate.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

For warnings regarding lactose and sodium content, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Hard gelatin capsule.

Red cap/red body, size '0' hard gelatin capsule containing white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Celecoxib is indicated in adults for the symptomatic relief in the treatment of osteoarthritis, rheumatoid arthritis and ankylosing spondylitis.

The decision to prescribe a selective cyclooxygenase-2 (COX-2) inhibitor should be based on an assessment of the individual patient's overall risks (see sections 4.3 and 4.4).

4.2 Posology and method of administration

General

As the cardiovascular risks of celecoxib may increase with dose and duration of exposure, the shortest duration possible and the lowest effective daily dose should be used. The patient's need for symptomatic relief and response to therapy should be re-evaluated periodically, especially in patients with osteoarthritis.

Osteoarthritis

The usual recommended daily dose is 200 mg taken once daily or in two divided doses. In some patients with insufficient relief from symptoms, an increased dose of 200 mg twice daily may increase efficacy. In the absence of an increase in therapeutic benefit after two weeks, other therapeutic options should be considered.

Rheumatoid arthritis

The initial recommended daily dose is 200 mg taken in two divided doses. The dose may, if needed, later be increased to 200 mg twice daily. In the absence of an increase in therapeutic benefit after two weeks, other therapeutic options should be considered.

Ankylosing spondylitis

The recommended daily dose is 200 mg taken once daily or in two divided doses. In a few patients with insufficient relief, an increased dose of 400 mg once daily or in two divided doses may increase efficacy. In the absence of an increase in therapeutic benefit after two weeks, other therapeutic options should be considered.

The maximum recommended daily dose is 400 mg for all indications.

Elderly

As in younger adults, 200 mg per day should be used initially. The dose may, if needed, later be increased to 200 mg twice daily. Particular caution should be exercised in elderly patients with a body weight less than 50 kg.

Paediatric population

Celecoxib is not indicated for use in children.

CYP2C9 poor metabolisers

Patients who are known or suspected to be CYP2C9 poor metabolisers should be administered celecoxib with caution. Consider reducing the dose to half the lowest recommended dose.

Hepatic impairment

Treatment should be initiated at half the recommended dose in patients with established moderate hepatic impairment with a serum albumin of 25–35 g/l. Celecoxib is contraindicated in severe hepatic dysfunction (serum albumin <25 g/l).

Renal impairment

Experience with celecoxib in patients with mild or moderate renal impairment is limited; such patients should be treated with caution. Celecoxib is contraindicated in patients with estimated creatinine clearance <30 ml/min.

Method of administration

Oral. Celecoxib may be taken with or without food. For patients who have difficulty swallowing capsules, the entire capsule contents may be emptied onto a level teaspoon of cool or room-temperature applesauce, rice gruel, yogurt or mashed banana and ingested immediately with 240 ml of water. The sprinkled capsule contents on applesauce, rice gruel or yogurt are stable for up to 6 hours under refrigerated conditions (2–8°C). The sprinkled capsule contents on mashed banana should not be stored under refrigerated conditions and should be ingested immediately.

4.3 Contraindications

- Hypersensitivity to the active substance, known hypersensitivity to sulphonamides, or to any of the excipients listed in section 6.1.
- Active peptic ulceration or gastrointestinal (GI) bleeding.
- Patients who have experienced asthma, acute rhinitis, nasal polyps, angioneurotic oedema, urticaria or other allergic-type reactions after taking acetylsalicylic acid (aspirin) or other NSAIDs including COX-2 inhibitors.
- Pregnancy and in women of childbearing potential unless using an effective method of contraception. Celecoxib has been shown to cause malformations in two animal species studied; the potential for human risk in pregnancy is unknown but cannot be excluded.
- Breast-feeding.
- Severe hepatic dysfunction (serum albumin <25 g/l or Child-Pugh score ≥10).
- Patients with estimated creatinine clearance <30 ml/min.
- Inflammatory bowel disease.
- Congestive heart failure (NYHA II–IV).
- Established ischaemic heart disease, peripheral arterial disease and/or cerebrovascular disease.

4.4 Special warnings and precautions for use

Gastrointestinal effects

Upper and lower gastrointestinal complications (perforations, ulcers or bleedings — PUBs), some resulting in fatal outcome, have occurred with celecoxib. Caution is advised in patients most at risk: the elderly; patients using other NSAIDs, antiplatelet drugs or glucocorticoids concomitantly; patients using alcohol; or patients with a prior history of gastrointestinal disease. There is a further increase in GI risk when celecoxib is taken concomitantly with low-dose acetylsalicylic acid. Concomitant use of celecoxib with a non-aspirin NSAID should be avoided.

Cardiovascular effects

Increased numbers of serious cardiovascular (CV) events, mainly myocardial infarction, have been observed in long-term placebo-controlled studies of celecoxib at doses of 200 mg twice daily and 400 mg twice daily in subjects with sporadic adenomatous polyps. As the cardiovascular risks of celecoxib may increase with dose and duration of exposure, the shortest duration possible and the lowest effective daily dose should be used. Patients with significant risk factors for cardiovascular events should only be treated with celecoxib after careful consideration. COX-2 selective inhibitors are not a substitute for acetylsalicylic acid for prophylaxis of cardiovascular thromboembolic diseases. Antiplatelet therapies should not be discontinued.

PRECISION trial results

The PRECISION study demonstrated that celecoxib at the lowest approved dose (100 mg twice daily) is non-inferior to ibuprofen 600–800 mg three times daily or naproxen 375–500 mg twice daily with respect to cardiovascular adverse effects in OA/RA patients with or at high risk for cardiovascular disease. The cardiovascular risks of the NSAID class are dose-dependent; results for 200 mg/day cannot be extrapolated to higher doses.

Fluid retention and oedema

Fluid retention and oedema have been observed in patients taking celecoxib. Use with caution in patients with history of cardiac failure, left ventricular dysfunction or hypertension, pre-existing oedema, or those taking diuretics or at risk of hypovolaemia.

Hypertension

As with all NSAIDs, celecoxib can lead to the onset of new hypertension or worsening of pre-existing hypertension. Blood pressure should be monitored closely during initiation of therapy and throughout the course of therapy.

Hepatic and renal effects

NSAIDs, including celecoxib, may cause renal toxicity. Patients at greatest risk include those with impaired renal function, heart failure, liver dysfunction, those taking diuretics, ACE inhibitors or ARBs, and the elderly. Some cases of severe hepatic reactions, including fulminant hepatitis (some with fatal outcome), liver necrosis and hepatic failure have been reported, mostly within one month of treatment initiation.

CYP2D6 inhibition

Celecoxib inhibits CYP2D6. A dose reduction may be necessary for individually dose-titrated medicinal products metabolised by CYP2D6.

CYP2C9 poor metabolisers

Patients known to be CYP2C9 poor metabolisers should be treated with caution.

Skin and systemic hypersensitivity reactions

Serious skin reactions, some fatal, including exfoliative dermatitis, SJS and TEN have been reported very rarely. Serious hypersensitivity reactions including anaphylaxis, angioedema and DRESS have also been reported. Celecoxib should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Use with oral anticoagulants

Serious bleeding events, some fatal, have been reported with concurrent warfarin therapy. Closely monitor prothrombin time (INR), particularly when celecoxib is initiated or the dose is changed. Exercise caution with novel anticoagulants (apixaban, dabigatran, rivaroxaban).

Lactose content

This medicinal product contains 120 mg lactose monohydrate per capsule. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Sodium content

This medicine contains less than 1 mmol sodium (23 mg) per capsule and is essentially 'sodium-free'.

4.5 Interaction with other medicinal products and other forms of interaction

Anticoagulants (warfarin, novel oral anticoagulants):

Anticoagulant activity should be monitored, particularly in the first few days after initiating or changing the celecoxib dose. Bleeding events in association with increases in prothrombin time have been reported, predominantly in the elderly.

Antihypertensives (ACE inhibitors, ARBs, diuretics, beta-blockers):

NSAIDs may reduce the antihypertensive effect. Risk of acute renal insufficiency may be increased in patients with compromised renal function when ACE inhibitors, ARBs and/or diuretics are combined with celecoxib. Use with caution; ensure adequate hydration; monitor renal function.

Ciclosporin and tacrolimus:

Co-administration may increase nephrotoxic effects. Monitor renal function.

Acetylsalicylic acid (aspirin):

Celecoxib can be used with low-dose aspirin but is not a substitute for aspirin for cardiovascular prophylaxis. Concomitant use increases the risk of GI ulceration or other GI complications.

CYP2D6 inhibition (celecoxib effect on other drugs):

Celecoxib is a CYP2D6 inhibitor. Plasma concentrations of CYP2D6 substrates (antidepressants, neuroleptics, antiarrhythmics) may be increased. Doses of individually dose-titrated CYP2D6 substrates may need to be reduced.

CYP2C19 inhibition:

In vitro studies show potential for celecoxib to inhibit CYP2C19. The clinical significance is unknown.

Methotrexate:

No statistically significant effect on methotrexate pharmacokinetics in RA patients. Monitor for methotrexate-related toxicity.

Lithium:

Co-administration resulted in mean increases in lithium Cmax of 16% and AUC of 18%. Monitor patients on lithium closely.

Fluconazole (CYP2C9 inhibitor):

Celecoxib should be used at half the recommended dose when co-administered with fluconazole. Combinations of CYP2C9 inhibitors with celecoxib should be avoided in known CYP2C9 poor metabolisers.

CYP2C9 inducers (rifampicin, carbamazepine, barbiturates):

May reduce plasma concentrations of celecoxib.

4.6 Fertility, pregnancy and lactation

Pregnancy

Celecoxib is contraindicated in pregnancy and in women who can become pregnant. Animal studies (rats and rabbits) have shown reproductive toxicity including malformations. Inhibition of prostaglandin synthesis may adversely affect pregnancy. Celecoxib, as with other NSAIDs, may cause uterine inertia and premature closure of the ductus arteriosus during the last trimester. During the second or third trimester, celecoxib may cause foetal renal dysfunction which may result in reduction of amniotic fluid volume or oligohydramnios. Such effects may occur shortly after treatment initiation and are usually reversible upon discontinuation. If a woman becomes pregnant during treatment, celecoxib should be discontinued.

Breast-feeding

Celecoxib is excreted in the milk of lactating rats at concentrations similar to those in plasma. Administration of celecoxib to a limited number of lactating women has shown very low transfer into breast milk. Celecoxib is contraindicated during breast-feeding.

Fertility

Based on the mechanism of action, the use of NSAIDs including celecoxib may delay or prevent rupture of ovarian follicles, which has been associated with reversible infertility in some women.

4.7 Effects on ability to drive and use machines

Celecoxib may have minor influence on the ability to drive and use machines. Patients who experience dizziness, vertigo or somnolence while taking celecoxib should refrain from driving or operating machinery.

4.8 Undesirable effects

Summary of the safety profile

The adverse reaction profile of celecoxib reflects data from placebo- and active-controlled trials in osteoarthritis and rheumatoid arthritis patients, long-term polyp prevention trials (APC and PreSAP), and post-marketing surveillance representing an estimated >70 million patients treated.

Tabulated list of adverse reactions

Frequencies: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known.

System Organ Class	Common	Uncommon	Rare / Very Rare / Not Known
Infections and infestations	Sinusitis, URTI, pharyngitis, UTI		
Blood and lymphatic disorders		Anaemia	Leukopenia, thrombocytopenia (rare); pancytopenia (very rare)
Immune system disorders	Hypersensitivity		Anaphylactic shock, anaphylactic reaction (very rare)
Metabolism and nutrition disorders		Hyperkalaemia	
Psychiatric disorders	Insomnia	Anxiety, depression, fatigue	Confusional state, hallucinations (rare)

System Organ Class	Common	Uncommon	Rare / Very Rare / Not Known
Nervous system disorders	Dizziness, hypertonia, headache[1]	Cerebrovascular infarction[1], paraesthesia, somnolence	Ataxia, dysgeusia (rare); intracranial haemorrhage[1] (very rare), aseptic meningitis (very rare)
Eye disorders		Vision blurred, conjunctivitis	Eye haemorrhage (rare); retinal artery/vein occlusion (very rare)
Ear and labyrinth disorders		Tinnitus, hypoacusis[1]	
Cardiac disorders	Myocardial infarction[1]	Cardiac failure, palpitations, tachycardia	Arrhythmia (rare)
Vascular disorders	Hypertension[1] (including aggravated)		Pulmonary embolism (rare), flushing (rare); vasculitis (very rare)
Respiratory disorders	Rhinitis, cough, dyspnoea[1]	Bronchospasm (rare)	Pneumonitis (rare)
Gastrointestinal disorders	Nausea, abdominal pain, diarrhoea, dyspepsia, flatulence, vomiting[1], dysphagia[1]	Constipation, gastritis, stomatitis, GI inflammation, eructation	GI haemorrhage (rare), GI ulceration (rare), perforation (rare), pancreatitis (rare)
Hepatobiliary disorders		Hepatic function abnormal, hepatic enzyme increased (SGOT/SGPT)	Hepatitis (rare); hepatic failure, fulminant hepatitis, hepatic necrosis, cholestasis (very rare)
Skin disorders	Rash, pruritus	Urticaria, ecchymosis	Angioedema, alopecia, photosensitivity (rare); TEN, SJS, DRESS, AGEP (very rare)
Musculoskeletal disorders	Arthralgia[1]	Muscle spasms (leg cramps)	Myositis (very rare)
Renal and urinary disorders		Blood creatinine increased, blood urea increased	Acute renal failure, hyponatraemia (rare); tubulointerstitial nephritis (very rare)
Reproductive and breast disorders			Menstrual disorder (rare); female infertility (not known)
General disorders	Influenza-like illness, peripheral oedema/fluid retention	Face oedema, chest pain	

[1] Adverse drug reactions that occurred in the APC and PreSAP polyp prevention trials (subjects receiving celecoxib 400 mg daily for up to 3 years).

Cardiovascular data from APC/PreSAP trials: Excess rate over placebo for myocardial infarction was 7.6 events per 1,000 patients (uncommon) with celecoxib 400 mg daily for up to 3 years; no excess rate for stroke over placebo.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

There is no clinical experience of overdose. Single doses up to 1,200 mg and multiple doses up to 1,200 mg twice daily have been administered to healthy subjects for nine days without clinically significant adverse effects. In the event of suspected overdose, provide appropriate supportive medical care (e.g. eliminating gastric contents, clinical supervision and, if necessary, symptomatic treatment). Dialysis is unlikely to be efficient due to high protein binding (approximately 97%).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Non-steroidal anti-inflammatory and antirheumatic drugs; NSAIDs; Coxibs. ATC code: M01AH01.

Mechanism of action

Celecoxib is an oral, selective COX-2 inhibitor within the clinical dose range (200–400 mg daily). No statistically significant inhibition of COX-1 was observed in healthy volunteers at this dose range. COX-2 is induced by pro-inflammatory stimuli and is primarily responsible for the synthesis of prostanoid mediators of pain, inflammation and fever. COX-2 selective inhibitors reduce formation of systemic and endothelial prostacyclin without affecting platelet thromboxane. Celecoxib is a diaryl-substituted pyrazole, chemically similar to non-arylamine sulfonamides but differs from arylamine sulfonamides.

Clinical efficacy and safety — PRECISION trial

The PRECISION study (N=24,081) compared celecoxib 200–400 mg daily with naproxen 750–1,000 mg daily and ibuprofen 1,800–2,400 mg daily in OA/RA patients with or at high risk for cardiovascular disease. Celecoxib met all four pre-specified non-inferiority requirements for the primary composite endpoint (cardiovascular death, non-fatal MI, non-fatal stroke) vs both comparators. These results indicate that celecoxib at the lowest approved dose (100 mg twice daily) is non-inferior to ibuprofen or naproxen at approved doses with respect to cardiovascular adverse effects. The cardiovascular risks of the NSAID class are dose-dependent.

5.2 Pharmacokinetic properties

Absorption

Celecoxib is well absorbed, reaching peak plasma concentrations approximately 2–3 hours after dosing. A high-fat meal delays absorption by approximately 1 hour (Tmax ≈4 hours) and increases bioavailability by approximately 20%.

Distribution

Plasma protein binding approximately 97% at therapeutic concentrations; not preferentially bound to erythrocytes.

Biotransformation

Celecoxib metabolism is primarily mediated via CYP2C9. Three inactive metabolites identified: a primary alcohol, the corresponding carboxylic acid and its glucuronide conjugate. Individuals homozygous for CYP2C9*3 show approximately 4-fold higher Cmax and 7-fold higher AUC (day 7) vs other genotypes. The plasma concentration of celecoxib is approximately 100% higher in elderly women (>65 years). In moderate hepatic impairment, Cmax increases 41% and AUC increases 146%.

Elimination

Mainly eliminated by metabolism. Less than 1% excreted unchanged in urine. Elimination half-life 8–12 hours. Steady state reached within 5 days. Inter-subject variability in exposure approximately 10-fold.

5.3 Preclinical safety data

Non-clinical safety data revealed no special hazard for humans based on conventional studies of repeated dose toxicity, mutagenicity or carcinogenicity. In rabbits, celecoxib at doses ≥150 mg/kg/day caused ventricular septal defects, fused ribs and sternebrae misshapen. In rats, doses ≥30 mg/kg/day caused a dose-dependent increase in diaphragmatic hernias during organogenesis. These effects are expected following inhibition of prostaglandin synthesis. Pup toxicity was observed in a peri-postnatal study in rats.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The following excipients are present in the hard gelatin capsule:

No.	Excipient
1	Lactose monohydrate (excipient with known effect — 120 mg per capsule)
2	Sodium lauryl sulphate
3	Purified talc
4	Magnesium stearate
5	Croscarmellose sodium

6.2 Incompatibilities

Not applicable.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store at a temperature not exceeding 30°C. Protect from light and moisture. Keep out of the reach and sight of children.

6.5 Nature and contents of container
1 ALU-ALU blister of 10 capsules; 1 such blister packed in a carton with package insert. Pack size: 10 capsules.

6.6 Special precautions for disposal and other handling
Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
NATIONAL PHARMACY LTD

P.O. Box 17843-00500, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)
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17.12.2026

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