Diclofenac

Class: Nonsteroidal Anti-inflammatory Drug (NSAID)

Indications: Capsule: Relief of mild-to-moderate acute pain

Immediate-release tablet: Relief of mild-to-moderate pain; primary dysmenorrhea; acute and chronic treatment of rheumatoid arthritis, osteoarthritis

Delayed-release tablet: Acute and chronic treatment of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis

Extended-release tablet: Chronic treatment of osteoarthritis, rheumatoid arthritis

Oral solution: Treatment of acute migraine with or without aura

Suppository (CAN; not available in U.S.): Symptomatic treatment of rheumatoid arthritis and osteoarthritis (including degenerative joint disease of hip)

Topical gel 1%: Relief of osteoarthritis pain in joints amenable to topical therapy (eg, ankle, elbow, foot, hand, knee, wrist)

Canadian labeling (not in U.S. labeling): Relief of pain associated with acute, localized joint/muscle injuries (eg, sports injuries, strains) in patients ≥16 years of age

Topical gel 3%: Actinic keratosis (AK) in conjunction with sun avoidance

Eye drops: Treatment of postoperative inflammation following cataract extraction; temporary relief of pain and photophobia in patients undergoing corneal refractive surgery.

Use - Unlabeled: Juvenile idiopathic arthritis (JIA)

Available dosage form in the hospital: Tablet, oral, as sodium: 50 mg, 75 mg.

Suppository, as sodium: 12.5 mg, 50 mg, 100 mg.

Injection: 75 mg.

Eye drop: 0.1%.

Gel: 1%

Cream, as sodium: 1% + menthol 2.5% + camphor 1.4%.

Trade Names:

Dosage: Analgesia: Oral:

Immediate release tablet: Starting dose: 50 mg 3 times/day (maximum dose: 150 mg/day); may administer 100 mg loading dose, followed by 50 mg every 8 hours (maximum dose day 1: 200 mg/day; maximum dose day 2 and thereafter: 150 mg/day)
**Canadian labeling:** Maximum loading dose day 1: 200 mg/day; maximum dose day 2 and up to 7 days: 150 mg/day (50 mg every 6-8 hours)

Immediate release capsule: 25 mg 4 times/day

**Primary dysmenorrhea:** Oral: Immediate release tablet: Starting dose: 50 mg 3 times/day (maximum dose: 150 mg/day); may administer 100 mg loading dose, followed by 50 mg every 8 hours

**Canadian labeling:** Maximum loading dose day 1: 200 mg/day; maximum dose day 2 and up to 7 days: 150 mg/day (50 mg every 6-8 hours)

**Rheumatoid arthritis:**

Oral: Immediate release tablet: 150-200 mg/day in 3-4 divided doses; Delayed release tablet: 150-200 mg/day in 2-4 divided doses; Extended release tablet: 100 mg/day (may increase dose to 200 mg/day in 2 divided doses)

**Canadian labeling:** 150 mg/day in 3 divided doses (75-150 mg/day of slow release tablet)

Rectal suppository (not available in U.S.): **Canadian labeling:** Insert 50 mg or 100 mg rectally as single dose to substitute for final (third) oral daily dose (maximum combined dose [rectal and oral]: 150 mg/day)

**Osteoarthritis:**

Oral: Immediate release tablet: 150-200 mg/day in 3-4 divided doses; Delayed release tablet: 150-200 mg/day in 2-4 divided doses; Extended release tablet: 100 mg/day; may increase dose to 200 mg/day in 2 divided doses

**Canadian labeling:** 150 mg/day in 3 divided doses (75-150 mg/day of slow release tablet)

Rectal suppository (not available in U.S.): **Canadian labeling:** Insert 50 mg or 100 mg rectally as single dose to substitute for final (third) oral daily dose (maximum combined dose [rectal and oral]: 150 mg/day)

**Topical gel (Voltaren®): Note:** Maximum total body dose of 1% gel should not exceed 32 g per day

Lower extremities: Apply 4 g of 1% gel to affected area 4 times/day (maximum: 16 g per joint per day)

Upper extremities: Apply 2 g of 1% gel to affected area 4 times/day (maximum: 8 g per joint per day)

**Ankylosing spondylitis:** Oral: Delayed release tablet: 100-125 mg/day in 4-5 divided doses

**Migraine:** Oral: Oral solution: 50 mg (one packet) as a single dose at the time of migraine onset; safety and efficacy of a second dose have not been established
**Actinic keratosis (AK):** Topical (Solaraze® Gel): Apply 3% gel to lesion area twice daily for 60-90 days.

**Acute pain (strains, sprains, contusions):** Topical:

Gel (Voltaren® Emulgel™ [CAN; not available in U.S.]): Apply 2-4 g to the skin over affected area(s) 3 or 4 times/day for up to 7 days.

**Cataract surgery:** Ophthalmic: Instill 1 drop into affected eye 4 times/day beginning 24 hours after cataract surgery and continuing for 2 weeks.

**Corneal refractive surgery:** Ophthalmic: Instill 1-2 drops into affected eye within the hour prior to surgery, within 15 minutes following surgery, and then continue for 4 times/day, up to 3 days.

**Common side effects:** Oral:

Cardiovascular: Edema

Central nervous system: Dizziness, headache

Dermatologic: Pruritus, rash

Endocrine & metabolic: Fluid retention

Gastrointestinal: Abdominal distension, abdominal pain, constipation, diarrhea, dyspepsia, flatulence, GI perforation, heartburn, nausea, peptic ulcer/GI bleed, vomiting

Hematologic: Anemia, bleeding time increased

Hepatic: Liver enzyme abnormalities (>3 x ULN; ≤4%)

Otic: Tinnitus

Renal: Renal function abnormal

Miscellaneous: Diaphoresis increased

**Local:** Application site reactions (incidence increased with 3% gel): Pruritus (≤52%), rash (35% to 46%), contact dermatitis (4% to 33%), dry skin (≤27%), pain (15% to 26%), exfoliation (3% gel; 6% to 24%), paresthesia (≤20%)

**Ocular:** Lacrimation (30%), keratitis (28%), intraocular pressure increased (15%), transient burning/stinging (15%)

**Pregnancy Risk Factor:** C (oral)/D (≥30 weeks gestation [oral])

B (topical gel 3%) / C (topical gel 1%) / D (topical solution ≥30 weeks gestation)

C (ophthalmic)