Detail drug information on Naproxen

Class: Analgesics, musculoskeletal agent

Mechanism of action:

- Naproxen is a propionic acid derivative NSAID with analgesic, anti-inflammatory, and antipyretic activities.
- The mechanism of action is unknown but involves inhibition of cyclooxygenase (COX-1 and COX-2), which leads to reduced prostaglandin synthesis.

Pharmacokinetics:

❖ Absorption

- Oral, tablet: time to peak concentration, 2 h to 4 h
- Oral, suspension: time to peak concentration, 1 h to 4 h
- Oral, delayed release tablet: time to peak concentration, 4 h to 6 h (2 h to 12 h)
- Bioavailability: 95%
- Effect of food: increases Tmax to 12 h (range 4 h to 24 h)

❖ Distribution:

- Vd: 0.16 L/kg
- Protein binding: greater than 99%

❖ Metabolism

- Extensive

❖ Excretion

- Renal: approximately 95%, less than 1% unchanged, less than 1% as metabolite
- Severe renal impairment: decreased excretion
- Dialyzable: no (hemodialysis)

❖ Elimination Half Life

- 12 to 17 hours

ADULT DOSING:

Gout, acute

- (Naprosyn(R) tablets) Initial, 750 mg orally followed by 250 mg every 8 hours until attack has subsided
- (Oral suspension) Initial, 750 mg (30 mL of 25 mg/mL suspension) orally followed by 250 mg (10 mL) every 8 hours until attack has subsided

Osteoarthritis

- (EC-Naprosyn(R) tablets) Initial, 375 or 500 mg orally twice daily; morning and evening dose do not need to be the same size. Titration, may adjust up or down based on clinical response, lower daily doses may suffice for long-term use. If lower dose is tolerated, a dose of 1500 mg/day may be used for up to 6 months if required (FDA dosage)

Adverse effects :

Common :

- **Cardiovascular:**
  Edema (3% to 9% .)
- **Dermatologic:**
  Ecchymosis (3% to 9%), Pruritus (3% to 9%), Rash (3% to 9%)
- **Gastrointestinal:**
  Abdominal pain (3% to 9%), Constipation (3% to 9%), Heartburn (3% to 9%), Nausea (3% to 9%)
- **Neurologic:**
  Dizziness (3% to 9%), Headache (3% to 9%), Somnolence (3% to 9%)
- **Otic:**
  Ototoxicity (3% to 9%), Tinnitus (3% to 9%)
- **Respiratory:**
  Dyspnea (3% to 9%)

Monitoring parameters:

- Rheumatoid arthritis/osteoarthritis: improved range of motion, decreased early morning stiffness and painful/swollen joints, C-reactive protein levels, erythrocyte sedimentation rate
- Acute gout/bursitis/dysmenorrhea/pain/tendonitis: relief of pain
- CBC and chemistry profiles; periodically for patients on long-term therapy
- Renal function; in elderly patients, those with renal or hepatic impairment, heart failure, hypovolemia, or dehydration
- Signs of worsening renal function; in patients with advanced renal disease
- Signs and symptoms of serious cardiovascular thrombotic events: throughout treatment

Medication counselling:

- Instruct patient to report symptoms of serious gastrointestinal events such as bleeding, ulceration, or perforation.
- Counsel patient to report symptoms of congestive heart failure, myocardial infarction, thrombotic events, or stroke
- Warn patient to report symptoms of hepatotoxicity (eg, hepatitis, hepatic failure).
- Tell patient to report symptoms of skin reactions such as rash, exfoliative dermatitis, Stevens-Johnson syndrome, or toxic epidermal necrolysis