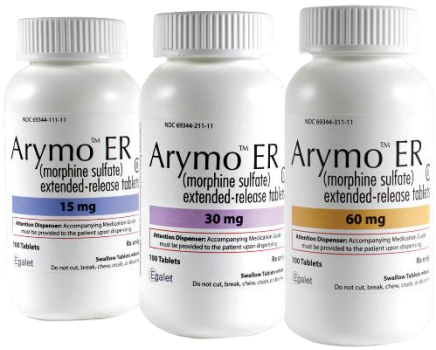
Arymo ER

(morphine sulfate)



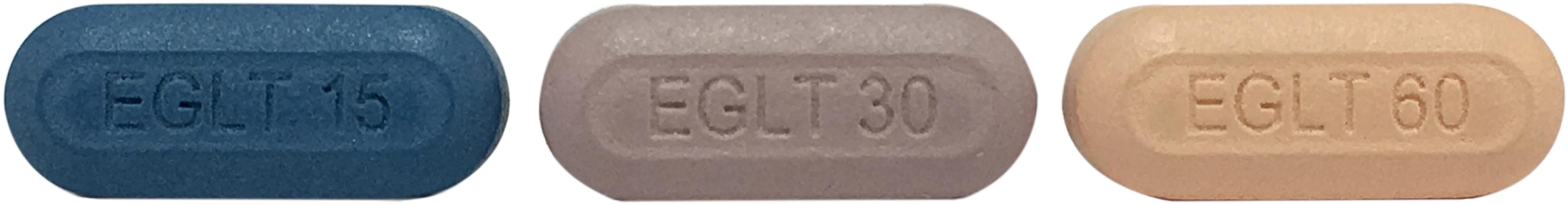
New Product Slideshow

MPR

Introduction

- **Brand name:** Arymo ER
- **Generic name:** Morphine sulfate
- **Pharmacological class:** Opioid agonist
- **Strength and Formulation:** 15mg, 30mg, 60mg; ext-rel tabs
- **Manufacturer:** Egalet
- **How supplied:** Bottle—100
- **Legal Classification:** CII

ARYMO ER



Indications

- Management of **pain** severe enough to require daily, around-the-clock, long-term opioid treatment for which alternative therapies are inadequate

Limitations of Use

- **Not for use** as an as-needed (prn) analgesic
- **Use only if** alternative treatment options (eg, non-opioid analgesics, immediate-release opioids) are ineffective, not tolerated, or otherwise inadequate to provide sufficient management of pain

Dosage & Administration

- Use lowest effective dose for shortest duration
- Swallow whole
- Individualize
- **Opioid-naive or opioid non-tolerant:** Initially 15mg every 8hrs or 12hrs
- Dosage adjustments may be made every 1–2 days

Dosage & Administration

- **Single dose >60mg or total daily dose >120mg:** for use in opioid-tolerant patients only
- Withdraw gradually by 25–50% every 2–4 days
- **Converting from other morphine formulations, other opioids:** see full labeling

Considerations for Special Populations

- **Pregnancy:** Potential neonatal opioid withdrawal syndrome during prolonged use
- **Nursing mothers:** Not recommended
- **Pediatric:** <18yrs: not established
- **Elderly:** May have increased sensitivity; caution with dose selection
- **Hepatic impairment:** Start at lower dose and titrate slowly in cirrhosis
- **Renal impairment:** Start at lower dose and titrate slowly in renal failure

Warnings/Precautions

- Abuse potential (monitor)
- Life-threatening **respiratory depression**; monitor within first 24–72hrs of initiating therapy and following dose increases
- Accidental exposure may cause **fatal overdose** (esp. in children)
- COPD, cor pulmonale, decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression; monitor and consider non-opioid analgesics

Warnings/Precautions

- Adrenal insufficiency
- Head injury
- Increased intracranial pressure, brain tumors; monitor
- Seizure disorders
- CNS depression
- Impaired consciousness, coma, shock; avoid
- Difficulty swallowing or risk for small GI lumen: consider alternative analgesic
- Biliary tract disease

Warnings/Precautions

- Acute pancreatitis
- Drug abusers
- Renal or hepatic impairment
- Reevaluate periodically
- Avoid abrupt cessation
- Elderly
- Cachectic
- Debilitated

Interactions

- See **Contraindications**
- **Increased risk** of hypotension, respiratory depression, sedation with benzodiazepines or other CNS depressants (eg, non-benzodiazepine sedatives/ hypnotics, anxiolytics, general anesthetics, phenothiazines, tranquilizers, muscle relaxants, antipsychotics, alcohol, other opioids); reserve concomitant use in those for whom alternative options are inadequate; limit dosages/durations to minimum required; monitor

Interactions

- **Avoid** concomitant mixed agonist/antagonist opioids (eg, butorphanol, nalbuphine, pentazocine) or partial agonist (eg, buprenorphine); may reduce effects and precipitate withdrawal symptoms
- Risk of **serotonin syndrome** with serotonergic drugs (eg, SSRIs, SNRIs, TCAs, triptans, 5-HT3 antagonists, mirtazapine, trazodone, tramadol, MAOIs, linezolid, IV methylene blue); monitor and discontinue if suspected

Interactions

- Monitor for **respiratory depression** with muscle relaxants, cimetidine, or P-gp inhibitors (eg, quinidine)
- **Paralytic ileus** may occur with anticholinergics
- May **antagonize** diuretics; monitor
- May increase serum amylase

Adverse Reactions

- Constipation
- Nausea
- Sedation
- Vomiting
- Sweating
- Dysphoria
- Euphoria
- Respiratory depression
- Orthostatic hypotension
- Syncope
- Hypersensitivity reactions

Mechanism of Action

- Morphine is a **full opioid agonist** and is relatively selective for the mu-opioid receptor, although it can bind to other opioid receptors at higher doses
- Specific CNS opioid receptors for endogenous compounds with opioid-like activity have been identified throughout the brain and spinal cord and are thought to play a role in the analgesic effects of this drug

Pharmacokinetics

- **Absorption:** Oral bioavailability approximately 20–40%
- **Distribution:** 30–35% reversibly bound to plasma proteins
- **Metabolism:** Glucuronidation, sulfation
- **Elimination:** Urine (major)

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/arymo-er/drug/34636/