

Extended Release/Long-Acting Opioids

General Drug Safety Information

This document is provided as a SUMMARY only of side effects and potential drug-drug interactions, for your reference as you prescribe ER/LA Opioids. Please consult the following for more information:

- www.er-la-opioidrems.com/lwgUl/rems/pdf/important_safety_information.pdf for general safety information
- www.er-la-opioidrems.com/lwgUl/rems/products.action for DETAILED product-specific information, including side effects and contraindications

ER/LA opioid analgesic products are scheduled under the Controlled Substances Act and can be misused and abused.

SIDE EFFECTS:

- **MOST COMMON:** Constipation. This should be anticipated, and discussed with your patients.
- **MOST SERIOUS:** Respiratory depression (RD). Patients should be monitored for respiratory depression. You should explain the relative risks and describe appropriate measure to take (including calling 911), as RD can be immediately life-threatening.

DRUG INTERACTIONS AND COMPLICATIONS:

- **CNS depressants.** ER/LA Opioids are also CNS depressants; combining them with any of the substances below can increase the sedation and respiratory depression effected by the opioids.
 - Alcohol
 - Sedatives
 - Hypnotics
 - Tranquilizers
 - Tricyclic antidepressants
- **“Dose Dumping”.** Exposure to alcohol may cause rapid release of some ER opioid formulations. Alcohol exposure may cause some opioid drug levels to increase, even without dose dumping.
- **MAOIs.** Use of opioids with MAOIs may result in possible increase in respiratory depression. Use of certain opioids with MAOIs may cause serotonin syndrome (interference with serotonin metabolism, resulting in neuromuscular, autonomic, and behavioral changes due to increased CNS serotonin activity)
- **Diuretics.** Opioids can reduce the efficacy of diuretics by inducing the release of antidiuretic hormone.
- **QTc interval.** Methadone and buprenorphine can prolong the QTc interval, increasing the risk of sudden cardiac death.
- **MRIs.** Patients should NOT wear transdermal fentanyl during MRIs (because of the metal foil backing on the patch)

TOLERANCE TO SEDATING AND RESPIRATORY-DEPRESSANT EFFECTS:

- Patients **MUST** be opioid tolerant before using any strength of
 - Transdermal fentanyl
 - ER hydromorphone
- Other ER/LA opioids require patients to be opioid tolerant before using
 - Certain strengths
 - Certain daily doses
- See FDA table for details