RESPONSIBLE OPIOID PRESCRIBING
ENGAGE EDUCATE PROTECT

Clinician Guide to the ER/LA Opioid Analgesics

Specific Drug Information for ER/LA Opioid Analgesic Products

Module VI

Jeffrey A. Gudin, MD
Director
Pain Management and Palliative Care
Englewood Hospital and Medical Center
Englewood, New Jersey

Overall Program Learning Objectives

Upon completion of this initiative, prescribers will be better able to:

- Identify and define how to assess patients for treatment with ER/LA opioid analgesics
- Demonstrate how to initiate therapy, modify dose and discontinue use of ER/LA opioid analgesics
- Recognize how to manage ongoing therapy with ER/LA opioid analgesics
- Employ patient and caregiver counseling about the safe use of ER/LA opioid analgesics, including proper storage and disposal
- **Recall** general and **product-specific drug information concerning ER/LA opioid analgesics**

Key Learning Points

- Specific characteristics of ER/LA opioid analgesic products; including the drug substance, formulation, strength, and dosing interval
- Key instructions on conversion information and specific drug interactions
- Initiating therapy; a review of opioid-tolerant patients, product-specific safety concerns of ER/LA opioid analgesics

Specific Characteristics

Critical information for the opioid products you prescribe:

Drug substance	Formulation	Strength	Dosing interval
Specific information about product conversions, if available		Specific drug interactions	
Key instructions	Use in opioid-tolerant patients	Product-specific safety concerns	Relative potency to morphine

For detailed information, refer to online PI:
DailyMed at www.dailymed.nlm.nih.gov
Drugs@FDA at www.fda.gov/drugsatfda

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www.fda.gov/downloads/drugs/drugsafety/informationbydrugclass/ucm277916.pdf

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Specific Characteristics: Tablets

Methadone Hydrochloride Tablets (Dolophine)

Dosing interval	• Every 8 to 12 hours
Key instructions	• Initial dose in opioid non-tolerant patients: 2.5 to 10 mg • Conversion of opioid-tolerant patients using equianalgesic tables can result in overdose and death. Use low doses according to table in full PI • High inter-patient variability in absorption, metabolism, and relative analgesic potency • Opioid detoxification or maintenance treatment only provided in a federally certified opioid (addiction) treatment program (CFR, Title 42, Sec 8)
Drug interactions	• Pharmacokinetic drug-drug interactions with methadone are complex – CYP 450 inducers may decrease methadone levels – CYP 450 inhibitors may increase methadone levels – Anti-retroviral agents have mixed effects on methadone levels • Potentially arrhythmogenic agents may increase risk for QTc prolongation and torsade de pointe • Benzodiazepines may increase respiratory depression

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Methadone Hydrochloride Tablets (Dolophine)

Opioid-tolerant	• Deaths have occurred in opioid-tolerant patients during conversion to methadone • Refer to full PI
Drug-specific safety concerns	• QTc prolongation and torsade de pointe • Peak respiratory depression occurs later and persists longer than analgesic effect • Clearance may increase during pregnancy • False-positive UDT possible • Major hazards include respiratory depression, systemic hypotension, respiratory arrest, cardiac arrest, and death
Relative potency: oral morphine	• Varies depending on patient's prior opioid experience

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Hydromorphone Hydrochloride ER Tablets (Exalgo)

Dosing interval	• Once a day
Key instructions	• Use conversion ratios in individual PI • Start patients with moderate hepatic impairment on 25% dose prescribed for patient with normal hepatic function • Start patients with moderate renal impairment on 50% and patients with severe renal impairment on 25% dose prescribed for patient with normal renal function • Titrate using a minimum of 3 to 4 d intervals • Swallow tablets whole (do not chew, crush, or dissolve) • Do not use in patients with sulfite allergy (contains sodium metabisulfite)
Drug interactions	• Mixed agonist/antagonist opioid analgesics, MAOIs, CNS depressants, anticholinergics
Opioid-tolerant	• All doses are indicated for opioid-tolerant patients only
Product-specific adverse reactions	• Allergic manifestations to sulfite component
Relative potency: oral morphine	• ~5:1 oral morphine to hydromorphone oral dose ratio, use conversion recommendations in individual product information

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Morphine Sulfate CR Tablets (MS Contin)

Dosing interval	• Every 8 hours or every 12 hours
Key instructions	• Product information recommends not using as first opioid • Titrate using a minimum of 1 to 2 day intervals • Swallow tablets whole (do not chew, crush, or dissolve)
Drug interactions	• CNS depressants (including alcohol) can increase the risk of respiratory depression, hypotension, profound sedation or coma • PGP inhibitors (eg, quinidine) may increase absorption/exposure of morphine by ~2-fold
Opioid-tolerant	• 100 mg and 200 mg tablet strengths for use in opioid-tolerant patients only
Product-specific safety concerns	• None

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Tapentadol ER Tablets (Nucynta ER)

Dosing interval	• Every 12 hours
Key instructions	• 50 mg every 12 hours is initial dose in opioid non-tolerant patients • Titrate by 50 mg increments using minimum of 3-day intervals • MDD: 500 mg • Swallow tablets whole (do not chew, crush, or dissolve) • Take 1 tablet at a time with enough water to ensure complete swallowing immediately after placing in mouth • Initiate dose using 50 mg once/day in moderate hepatic impairment (100 mg/day max) • Avoid use in severe hepatic and renal impairment
Drug interactions	• Alcoholic beverages or medications with alcohol may result in rapid release and absorption of a potentially fatal dose of tapentadol • Contraindicated in patients taking MAOIs • Monitor for signs of serotonin syndrome when using with SSRIs, SNRIs, tricyclic antidepressants and triptans
Opioid-tolerant	• No product-specific considerations
Product-specific safety concerns	• Risk of serotonin syndrome • Contraindicated with hypersensitivity (eg, angio-edema, anaphylaxis) to tapentadol or other ingredients
Relative potency: oral morphine	• Equipotency to oral morphine has not been established

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Oxymorphone Hydrochloride ER Tablets (Opana ER)

Dosing interval	• Every 12 hour dosing, some may benefit from asymmetric (different dose given in AM than in PM) dosing
Key instructions	• Use 5 mg every 12 hours as initial dose in opioid non-tolerant patients and patients with mild hepatic impairment and renal impairment (creatinine clearance <50 mL/min) and patients >65 years • Swallow tablets whole (do not chew, crush, or dissolve) • Take 1 tablet at a time, with enough water to ensure complete swallowing immediately after placing in mouth • Titrate using a minimum of 2-day intervals • Contraindicated in moderate and severe hepatic impairment • Administer on an empty stomach at least 1 hour prior to or 2 hours after eating
Drug interactions	• Alcoholic beverages or medications with alcohol may result in absorption of a potentially fatal dose of oxymorphone
Opioid-tolerant	• No product-specific considerations
Product-specific safety concerns	• None
Relative potency: oral morphine	• Approximately 3:1 oral morphine to oxymorphone oral dose ratio

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Oxycodone Hydrochloride CR Tablets (OxyContin)

Dosing interval	• Every 12 hours
Key instructions	• Opioid-naïve patients: initiate treatment with 10 mg every 12 hours • Titrate using a minimum of 1 to 2 day intervals • Hepatic impairment: start with ⅛ to ½ usual dosage followed by careful titration • Renal impairment (creatinine clearance <60 mL/min): follow a conservative approach to dose initiation and adjust accordingly • Consider other analgesics in patients with difficulty swallowing or underlying GI disorders that predispose to obstruction. Swallow tablets whole (do not chew, crush, or dissolve) • Take 1 tablet at a time, with enough water to ensure complete swallowing immediately after placing in mouth
Drug interactions	• CYP3A4 inhibitors may increase oxycodone exposure • CYP3A4 inducers may decrease oxycodone exposure
Opioid-tolerant	• Single dose >40 mg or total daily dose >80 mg for use in opioid-tolerant patients only
Product-specific safety concerns	• Choking, gagging, regurgitation, tablets stuck in throat, difficulty swallowing tablet • Contraindicated in patients with GI obstruction
Relative potency: oral morphine	• Approximately 2:1 oral morphine to oxycodone oral dose ratio

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Specific Characteristics: Capsules

Morphine Sulfate ER-Naltrexone Capsules (Embeda)*

Dosing interval	• Once a day or every 12 hours
Key instructions	• Initial dose as first opioid: 20 mg/0.8 mg • Titrate using a **minimum of 3-day intervals** • Swallow capsules whole (do not chew, crush, or dissolve) • Crushing or chewing will release morphine, possibly resulting in fatal overdose, and naltrexone, possibly resulting in withdrawal symptoms • May open capsule and sprinkle pellets on applesauce for patients who can reliably swallow without chewing, use immediately
Drug interactions	• Alcoholic beverages or medications with alcohol may result in rapid release and absorption of potentially fatal dose • PGP inhibitors (eg, quinidine) may increase absorption/exposure of morphine by ~2-fold
Opioid-tolerant	• 100 mg/4 mg capsule for use in opioid-tolerant patients only
Product-specific safety concerns	• None

*In March 2011, all dosage forms of EMBEDA® were voluntarily recalled by Pfizer; product availability expected in 2nd quarter 2014.

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Morphine Sulfate ER Capsules (Avinza)

Dosing interval	• Once a day
Key instructions	• *Initial dose in opioid non-tolerant patients is 30 mg* • Titrate using a minimum of 3-day intervals • Swallow capsule whole (do not chew, crush, or dissolve) • May open capsule and sprinkle pellets on applesauce for patients who can reliably swallow without chewing; use immediately • MDD*: 1600 mg (renal toxicity of excipient, fumaric acid)
Drug interactions	• Alcoholic beverages or medications with alcohol may result in rapid release and absorption of potentially fatal dose • PGP† inhibitors (eg, quinidine) may increase absorption/exposure of morphine by ~2-fold
Opioid-tolerant	• 90 mg and 120 mg capsules for use in opioid-tolerant patients only
Product-specific safety concerns	• None

*MDD=maximum daily dose; †PGP=P-glycoprotein

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Morphine Sulfate ER Capsules (Kadian)

Dosing interval	• Once a day or every 12 hours
Key instructions	• PI recommends not using as first opioid • Titrate using minimum of 1 to 2 day intervals • Swallow capsules whole (do not chew, crush, or dissolve) • May open capsule and sprinkle pellets on applesauce for patients who can reliably swallow without chewing, use immediately • Contents of capsules may be administered through a 16 French gastrostomy tube
Drug interactions	• Alcoholic beverages or medications with alcohol may result in rapid release and absorption of potentially fatal dose of morphine • PGP inhibitors (eg, quinidine) may increase absorption/exposure of morphine by ~2-fold
Opioid-tolerant	• 100 mg, 130 mg, 150 mg and 200 mg capsules for use in opioid-tolerant patients only
Product-specific safety concerns	• None

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Hydrocodone Bitartrate ER Capsules (Zohydro ER)*

Dosing interval	• **Every 12 hours**
Key instructions	• Opioid-naïve patients: initiate treatment with 10 mg every 12 hours • Titrate using a minimum of 2 to 4 day intervals • Severe hepatic impairment: start with the lowest dose, 10 mg, and monitor closely for respiratory depression and sedation • Renal impairment: initiate therapy with a low initial dose and monitor closely for respiratory depression and sedation • Take 1 capsule at a time, with enough water to ensure complete swallowing immediately after placing in mouth • Swallow capsules whole (do not chew, crush, or dissolve)
Drug interactions	• CYP3A4 inhibitors may increase hydrocodone exposure • CYP3A4 inducers may decrease hydrocodone exposure • Alcohol may result in increased plasma levels and a potentially fatal overdose of hydrocodone
Opioid-tolerant	• Single dose >40 mg or total daily dose >80 mg for use in opioid-tolerant patients only
Product-specific safety concerns	• Orthostatic hypotension and syncope
Relative potency: oral morphine	• Use conversion recommendations in individual product information

*October 2013, Zohydro ER, manufactured by Zogenix, was FDA approved; Zohydro ER will be available March 2014.

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Specific Characteristics: Transdermal Systems

Fentanyl Transdermal System (Duragesic)

Dosing interval	• Every 72 hours (3 days)
Key instructions	• Use product-specific information for dose conversion from prior opioid • Hepatic or renal impairment: use 50% of dose if mild/moderate, avoid use if severe • Application – Apply to intact/non-irritated/non-irradiated skin on a flat surface – Prep skin by clipping hair, washing site with water only – Rotate site of application – Titrate using no less than 72 hour intervals – Do not cut • Avoid exposing the application site to direct external heat sources due to potential overdose and death • Avoid accidental contact when holding or caring for children • Dispose of used/unused patches: fold adhesive side together and flush down toilet

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Fentanyl Transdermal System (Duragesic)

Key instructions	**Specific contraindications:** • Patients who are not opioid-tolerant • Management of – Acute or intermittent pain, or patients who require opioid analgesia for a short period of time – Postoperative pain, outpatient, or day surgery – Mild pain
Drug interactions	• CYP3A4 inhibitors may increase fentanyl exposure • CYP3A4 inducers may decrease fentanyl exposure
Opioid-tolerant	• All doses indicated for opioid-tolerant patients only
Drug-specific safety concerns	• Accidental exposure due to secondary exposure to unwashed/unclothed application site or inappropriate disposal • Increased drug exposure with increased core body temp or fever • Bradycardia • Application site skin reactions
Relative potency: oral morphine	• See individual PI for conversion recommendations from prior opioid

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Buprenorphine Transdermal System (Butrans)

Dosing interval	• One transdermal system every 7 days

Key instructions	• Initial dose in opioid non-tolerant patients on <30 mg morphine equivalents and in mild-moderate hepatic impairment: 5 mcg/hour
	• When converting from 30 mg to 80 mg morphine equivalents, first taper to 30 mg morphine equivalent, then initiate with 10 mcg/hour
	• Titrate after a minimum of 72 hours prior to dose adjustment
	• Maximum dose: 20 mcg/hour due to risk of QTc prolongation
	• Application
	  • Apply only to sites indicated in PI
	  • Apply to intact/non-irritated skin
	  • Prep skin by clipping hair; wash site with water only
	  • Rotate application site (minimum 3 weeks before reapply to same site)
	  • Do not cut
	• Avoid exposure to heat
	• Dispose of patches: fold adhesive side together and flush down toilet or use product-specific Patch Disposal Unit

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Buprenorphine Transdermal System (Butrans)

Drug interactions	• CYP3A4 inhibitors may increase buprenorphine levels • CYP3A4 inducers may decrease buprenorphine levels • Benzodiazepines may increase respiratory depression • Class IA and III antiarrhythmics, other potentially arrhythmogenic agents, may increase risk of QTc prolongation and torsade de pointe
Opioid-tolerant	• 10 mcg/hour and 20 mcg/hour for use in opioid-tolerant patients only
Drug-specific safety concerns	• QTc prolongation and torsade de pointe • Hepatotoxicity • Application site skin reactions
Relative potency: oral morphine	• Equipotency to oral morphine not established

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Specific Characteristics

Critical information for the opioid products you prescribe:

Drug substance	Formulation	Strength	Dosing interval
Specific information about product conversions, if available		Specific drug interactions	
Key instructions	Use in opioid-tolerant patients	Product-specific safety concerns	Relative potency to morphine

For detailed information, refer to online PI:
DailyMed at www.dailymed.nlm.nih.gov
Drugs@FDA at www.fda.gov/drugsatfda

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www.fda.gov/downloads/drugs/drugsafety/informationbydrugclass/ucm277916.pdf

Specific Characteristics

Know for opioid products you prescribe:

Drug substance			Dosing interval
Specific information a conversions, if a		interactions	
Key instructions	Use in opioid-tolerant patients	Product-specific safety concerns	Relative potency to morphine

Ensure patient knows and documents products prescribed.
Know the drug substance in each product prescribed.
Document decision to make drug substance choice.

For detailed information, refer to online PI:
DailyMed at www.dailymed.nlm.nih.gov
Drugs@FDA at www.fda.gov/drugsatfda

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www.fda.gov/downloads/drugs/drugsafety/informationbydrugclass/ucm277916.pdf

Specific Characteristics

Know for opioid products you prescribe:

Drug substance

Formulation

Communicate implications of formulations or changes to patients.
Know the formulation of each product prescribed.
Document formulation prescribed.

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Specific information about product conversions, if available

Key instructions

Use in opioid-tolerant patients

Product-specific safety concerns

Relative potency to morphine

For detailed information, refer to online PI:
DailyMed at www.dailymed.nlm.nih.gov
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Specific Characteristics

Know for u prescribe:

Clearly communicate prescribed strength and any changes to patients.
Know the strength of each product prescribed.
Document strength of product prescribed.

Drug substa

Strength

Dosing interval

Specific information about product conversions, if available

Specific drug interactions

Key instructions

Use in opioid-tolerant patients

Product-specific safety concerns

Relative potency to morphine

For detailed information, refer to online PI:
DailyMed at www.dailymed.nlm.nih.gov
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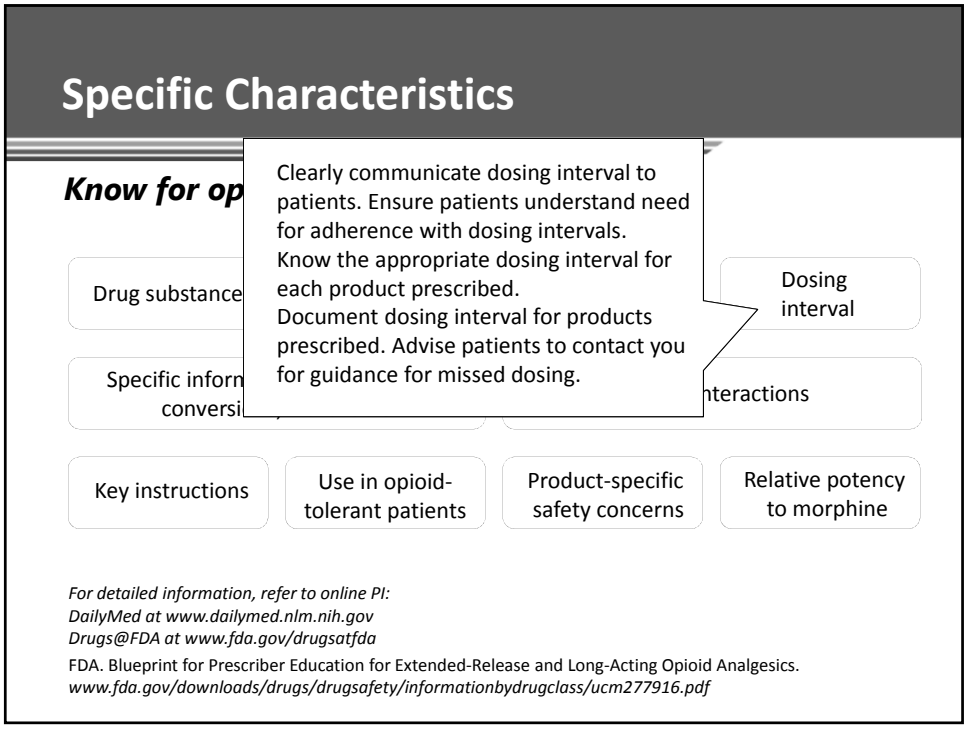
Specific Characteristics
Know for op
Clearly communicate dosing interval to patients. Ensure patients understand need for adherence with dosing intervals.
Know the appropriate dosing interval for each product prescribed.
Document dosing interval for products prescribed. Advise patients to contact you for guidance for missed dosing.
Drug substance
Dosing interval
Specific inform
conversi
nteractions
Key instructions
Use in opioid-tolerant patients
Product-specific safety concerns
Relative potency to morphine
For detailed information, refer to online PI:
DailyMed at www.dailymed.nlm.nih.gov
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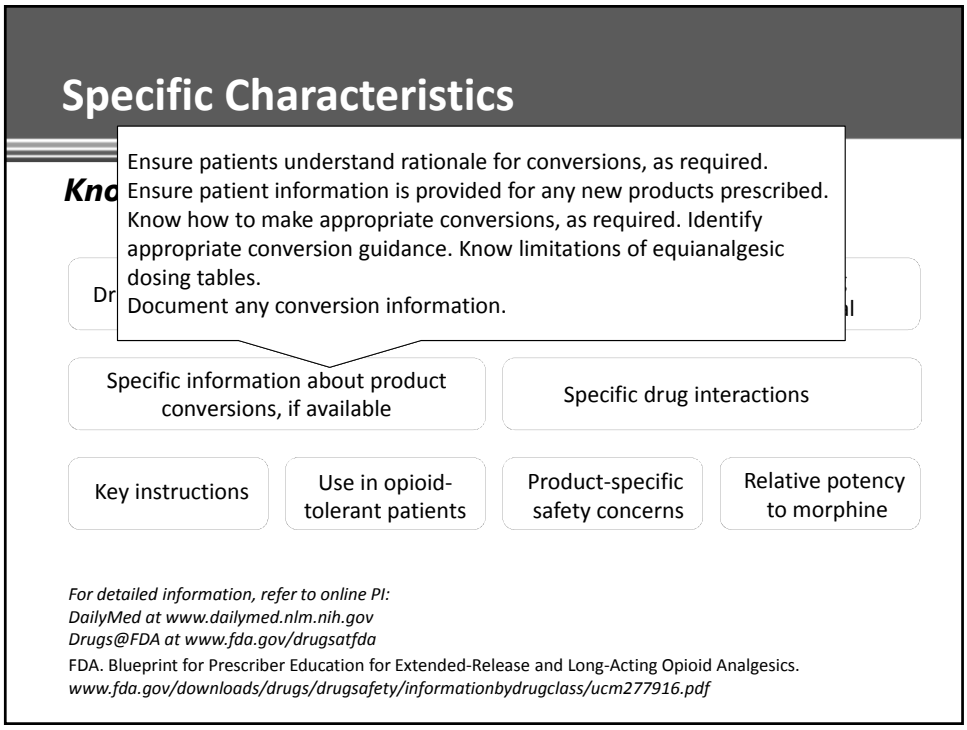
Specific Characteristics
Kno
Ensure patients understand rationale for conversions, as required.
Ensure patient information is provided for any new products prescribed.
Know how to make appropriate conversions, as required. Identify appropriate conversion guidance. Know limitations of equianalgesic dosing tables.
Document any conversion information.
Dr
l
Specific information about product conversions, if available
Specific drug interactions
Key instructions
Use in opioid-tolerant patients
Product-specific safety concerns
Relative potency to morphine
For detailed information, refer to online PI:
DailyMed at www.dailymed.nlm.nih.gov
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Specific Characteristics

Know for opioid pr

Communicate risks of interactions clearly to patients.
Ensure patients are aware of signs of respiratory depression.
Know specific drug interactions.
Document guidance on risk of interactions. Advise patients to contact you with concerns of interactions.

Drug substance

F

Specific information about product conversions, if available

Specific drug interactions

Key instructions

Use in opioid-tolerant patients

Product-specific safety concerns

Relative potency to morphine

For detailed information, refer to online PI:
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Specific Characteristics

Know for opioid products you prescribe:

Ensure patients are aware of any specific instructions for use/disposal.
Know key instructions for use for specific products.
Document key instructions shared with patients.

trength

Dosing interval

pecific drug interactions

Key instructions

Use in opioid-tolerant patients

Product-specific safety concerns

Relative potency to morphine

For detailed information, refer to online PI:
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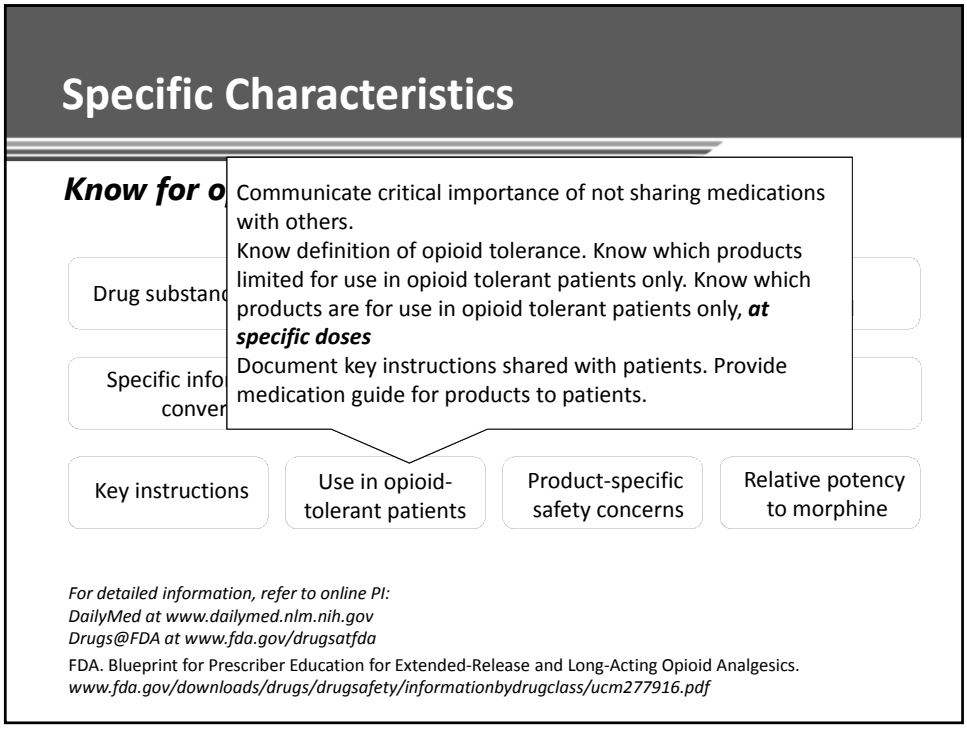
Specific Characteristics
Know for o
Communicate critical importance of not sharing medications with others.
Know definition of opioid tolerance. Know which products limited for use in opioid tolerant patients only. Know which products are for use in opioid tolerant patients only, at specific doses
Document key instructions shared with patients. Provide medication guide for products to patients.
Drug substanc
Specific info
conver
Key instructions
Use in opioid-tolerant patients
Product-specific safety concerns
Relative potency to morphine
For detailed information, refer to online PI:
DailyMed at www.dailymed.nlm.nih.gov
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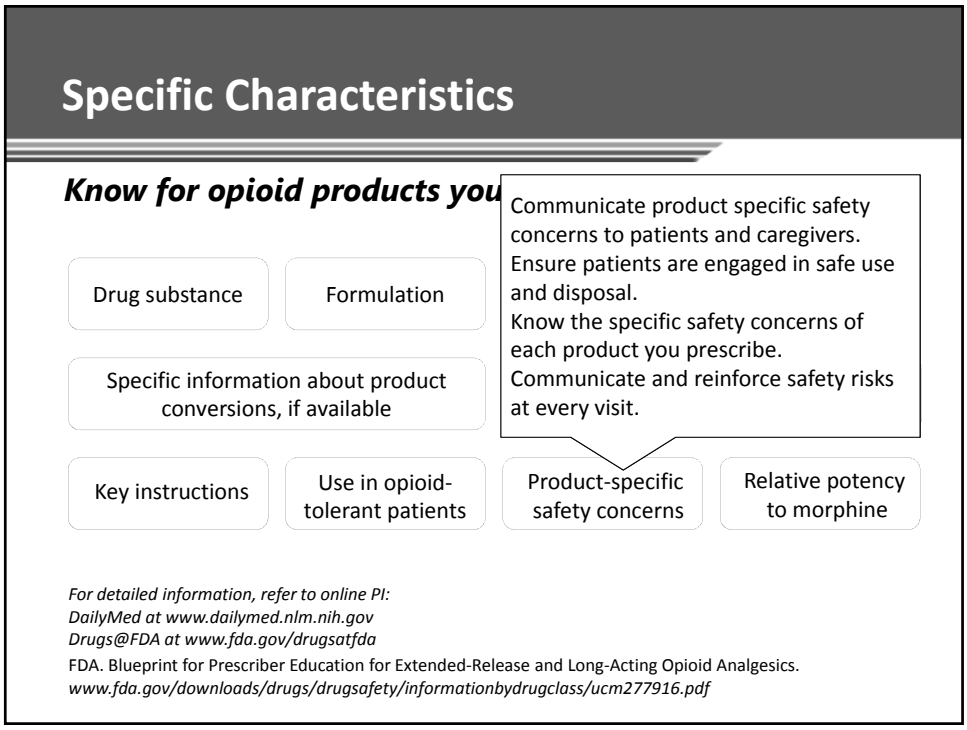
Specific Characteristics
Know for opioid products you
Communicate product specific safety concerns to patients and caregivers.
Ensure patients are engaged in safe use and disposal.
Know the specific safety concerns of each product you prescribe.
Communicate and reinforce safety risks at every visit.
Drug substance
Formulation
Specific information about product conversions, if available
Key instructions
Use in opioid-tolerant patients
Product-specific safety concerns
Relative potency to morphine
For detailed information, refer to online PI:
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Specific Characteristics

Know for opioid products you prescribe:

- Drug substance
- Formulation
- Strength
- Dosing
- Specific information about product conversions, if available
- Specific c
- Key instructions
- Use in opioid-tolerant patients
- Product-specific safety concerns
- Relative potency to morphine

Know the relative potency to morphine for every product you prescribe.

For detailed information, refer to online PI:
DailyMed at www.dailymed.nlm.nih.gov
Drugs@FDA at www.fda.gov/drugsatfda

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The Age of Responsible Opioid Prescribing

- Increased attention to chronic pain as a major public health problem, accompanied by increased opioid prescribing and prescription opioid abuse, morbidity, and mortality
- FDA mandated availability of prescriber education for long-acting and extended-release opioid analgesics

Novak S, et al. *Pain Med*. 2004;5(1):59-65.; FSMB. Responsible Opioid Prescribing: A Physician's Guide. *www.fsmb.org/pain-model-policy.html.* Accessed February 12, 2014.; Chou R, et al. *J Pain*. 2009:10(2):113-130.; FDA. Risk Evaluation and Mitigation Strategies (REMS) and Opioid Analgesics Webinar. *www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163655.htm*. Accessed February 12, 2014.

Thank you for completing Module 6.

You must answer the post-test questions at the end of this module in order to print your CE certificate