Section	Former Labeling Language	Changes (additions/changes in **bold underline**, deletions in ~~strikethrough~~)
HIGHLIGHTS OF PRESCRIBING INFORMATION		**Dosage and Administration** • **Periodically reassess patients receiving [TRADENAME] to evaluate the continued need for opioid analgesics to maintain pain control, the signs or symptoms of adverse reactions, and the development of addiction, abuse, or misuse. (2.x)**
	Dosage and Administration • Do not abruptly discontinue [TRADENAME] in a physically dependent patient because rapid discontinuation of opioid analgesics has resulted in serious withdrawal symptoms, uncontrolled pain, and suicide. (2.x, 5.x)	• Do not **rapidly reduce or** abruptly discontinue [TRADENAME] in a physically dependent patient because rapid **reduction or abrupt** discontinuation of opioid analgesics has resulted in serious withdrawal symptoms, uncontrolled pain, and suicide. (2.x, 5.x)
BOXED WARNING	• If opioid use is required for an extended period of time in a pregnant woman, advise the patient of the risk of Neonatal Opioid Withdrawal Syndrome, which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery. *[see Warnings and Precautions (5.x)]*	• ~~If opioid use is required for an extended period of time in a pregnant woman, advise the patient of the risk of NOWS,~~ **Advise pregnant women using opioids for an extended period of time of the risk of Neonatal Opioid Withdrawal Syndrome,** which may be life-threatening if not recognized and treated. Ensure that management by neonatology experts will be available at delivery *[see Warnings and Precautions (5.x)]*.
1 INDICATIONS AND USAGE	***ER/LA Opioid Analgesics***	
	[TRADENAME] is indicated for the management of severe and persistent pain that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate. <u>Limitations of Use</u> • Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration, and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations, *[see Warnings and Precautions (5.1)]*, reserve [TRADENAME] for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.	[TRADENAME] is indicated for the management of severe and persistent pain that requires an ~~extended treatment period with a daily~~ opioid analgesic and ~~for which alternative treatment options are inadequate~~ **that cannot be adequately treated with alternative options, including immediate-release opioids**. <u>Limitations of Use</u> • Because of the risks of addiction, abuse, ~~and~~ misuse**, overdose, and death** ~~with opioids~~, which can occur at any dosage or duration **and persist over the course of therapy** ~~and because of the greater risks of overdose and death with extended-release/long-acting opioid formulations~~ *[see Warnings and Precautions (5.1)]*, reserve **opioid analgesics, including** [TRADENAME], for use in patients for whom alternative treatment options ~~(e.g., non-opioid analgesics or immediate-release opioids)~~ are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.
	IR/SA Opioid Analgesics	

	Limitations of Use Because of the risks of addiction, abuse, and misuse with opioids, which can occur at any dosage or duration *[see Warnings and Precautions (5.1)]*, reserve [TRADENAME] for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or opioid combination products): • Have not been tolerated or are not expected to be tolerated, • Have not provided adequate analgesia or are not expected to provide adequate analgesia. [TRADENAME] should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.	Limitations of Use Because of the risks of addiction, abuse, ~~and~~ misuse**, overdose, and death** ~~with opioids~~, which can occur at any dosage or duration **and persist over the course of therapy** *[see Warnings and Precautions (5.1)]***,** reserve **opioid analgesics, including** [TRADENAME], for use in patients for whom alternative treatment options **are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.** ~~(e.g., non-opioid analgesics or non-opioid combination products):~~ ~~• Have not been tolerated or are not expected to be tolerated,~~ ~~• Have not provided adequate analgesia or are not expected to provide adequate analgesia.~~ ~~[TRADENAME] should not be used for an extended period of time unless the pain remains severe enough to require an opioid analgesic and for which alternative treatment options continue to be inadequate.~~
2 DOSAGE AND ADMINISTRATION	**2.2 Patient Access to Naloxone for the Emergency Treatment of Opioid Overdose** Discuss the availability of naloxone for the emergency treatment of opioid overdose with the patient and caregiver and assess the potential need for access to naloxone, both when initiating and renewing treatment with [TRADENAME] *[see Warnings and Precautions (5.x)]*. Inform patients and caregivers about the various ways to obtain naloxone as permitted by individual state naloxone dispensing and prescribing requirements or guidelines (e.g., by prescription, directly from a pharmacist, or as part of a community-based program). Consider prescribing naloxone, based on the patient's risk factors for overdose, such as concomitant use of CNS depressants, a history of opioid use disorder, or prior opioid overdose. The presence of risk factors for overdose should not prevent the proper management of pain in any given patient *[see Warnings and Precautions (5.x, 5.x, 5.x)]*. Consider prescribing naloxone if the patient has household members (including children) or other close contacts at risk for accidental ingestion or overdose.	**2.2 Patient Access to ~~Naloxone~~ an Opioid Overdose Reversal Agent for the Emergency Treatment of Opioid Overdose** *(Replace section text with the following language.)* **Inform patients and caregivers about opioid overdose reversal agents (e.g., naloxone, nalmefene). Discuss the importance of having access to an opioid overdose reversal agent, especially if the patient has risk factors for overdose (e.g., concomitant use of CNS depressants, a history of opioid use disorder, or prior opioid overdose) or if there are household members (including children) or other close contacts at risk for accidental ingestion or opioid overdose. The presence of risk factors for overdose should not prevent the management of pain in any patient *[see Warnings and Precautions (5.x, 5.x, 5.x)]*.** **Discuss the options for obtaining an opioid overdose reversal agent (e.g., prescription, over-the-counter, or as part of a community-based program) *[see Warnings and Precautions (5.x)]*.** **There are important differences among the opioid overdose reversal agents, such as route of administration, product strength, approved patient age range, and pharmacokinetics. Be familiar with these differences, as outlined in the approved labeling for those products, prior to recommending or prescribing such an agent.**
	2.x Safe Reduction or Discontinuation of [TRADENAME] Do not abruptly discontinue [TRADENAME] in patients who may be physically dependent on opioids.	**2.x Safe Reduction or Discontinuation of [TRADENAME]** Do not **rapidly reduce or** abruptly discontinue [TRADENAME] in patients who may be physically dependent on opioids.
		ER/LA Opioid Analgesics
	2.x Initial Dosing Use of [TRADENAME] as the First Opioid Analgesic (Opioid-Naïve Patients) ***[****drug-specific dosing instructions]*	**2.x Initial Dosing** ~~Use of [TRADENAME] as the First Opioid Analgesic (Opioid-Naïve Patients)~~ *Language regarding the use of an ER/LA opioid analgesic as the first opioid analgesic varies from product to product (an example is shown immediately above).*

		This change, indicated by ~~strikeout~~ in this table, will apply to all language in ER/LA labeling on this topic. All existing language suggesting that a given ER/LA opioid analgesic can be used in opioid-naïve patients will be removed from labeling.
5 WARNINGS AND PRECAUTIONS	**5.1 Addiction, Abuse, and Misuse** [TRADENAME] contains [drug], a Schedule II controlled substance. As an opioid, [TRADENAME] exposes users to the risks of addiction, abuse, and misuse *[see Drug Abuse and Dependence (9)]*. Because extended-release products such as [TRADENAME] deliver the opioid over an extended period of time, there is a greater risk for overdose and death due to the larger amount of [drug] present *[see Drug Abuse and Dependence (9)]*. Although the risk of addiction in any individual is unknown, it can occur in patients appropriately prescribed [TRADENAME]. Addiction can occur at recommended dosages and if the drug is misused or abused.	**5.1 Addiction, Abuse, and Misuse** [TRADENAME] contains [drug], a Schedule II controlled substance. As an opioid, [TRADENAME] exposes users to the risks of addiction, abuse, and misuse. ~~Because extended-release products such as [TRADENAME] deliver the opioid over an extended period of time, there is a greater risk for overdose and death due to the larger amount of [drug] present~~ *[see Drug Abuse and Dependence (9)]*. Although the risk of addiction in any individual is unknown, it can occur in patients appropriately prescribed [TRADENAME]. Addiction can occur at recommended doses and if the drug is misused or abused. **The risk of opioid-related overdose or overdose-related death is increased with higher opioid doses, and this risk persists over the course of therapy. In postmarketing studies, addiction, abuse, misuse, and fatal and non-fatal opioid overdose were observed in patients with long-term opioid use *[see Adverse Reactions (6.X)]*.**
	5.x Life-Threatening Respiratory Depression Patient Access to Naloxone for the Emergency Treatment of Opioid Overdose Discuss the availability of naloxone for the emergency treatment of opioid overdose with the patient and caregiver and assess the potential need for access to naloxone, both when initiating and renewing treatment with [TRADENAME]. Inform patients and caregivers about the various ways to obtain naloxone as permitted by individual state naloxone dispensing and prescribing requirements or guidelines (e.g., by prescription, directly from a pharmacist, or as part of a community-based program). Educate patients and caregivers on how to recognize respiratory depression and emphasize the importance of calling 911 or getting emergency medical help, even if naloxone is administered. Consider prescribing naloxone, based on the patient's risk factors for overdose, such as concomitant use of CNS depressants, a history of opioid use disorder, or prior opioid overdose. The presence of risk factors for overdose should not prevent the proper management of pain in any given patient. Also consider prescribing naloxone if the patient has household members (including children) or other close contacts at risk for accidental ingestion or overdose. If naloxone is prescribed, educate patients and caregivers on how to treat with naloxone *[see Dosage and Administration (2.x), Warnings and*	**5.x Life-Threatening Respiratory Depression** Patient Access to ~~Naloxone~~ **an Opioid Overdose Reversal Agent** for the Emergency Treatment of Opioid Overdose **Inform patients and caregivers about opioid overdose reversal agents (e.g., naloxone, nalmefene). Discuss the importance of having access to an opioid overdose reversal agent, especially if the patient has risk factors for overdose (e.g., concomitant use of CNS depressants, a history of opioid use disorder, or prior opioid overdose) or if there are household members (including children) or other close contacts at risk for accidental ingestion or opioid overdose. The presence of risk factors for overdose should not prevent the management of pain in any patient *[see Warnings and Precautions (5.x, 5.x)]*.** **Discuss the options for obtaining an opioid overdose reversal agent (e.g., prescription, over-the-counter, or as part of a community-based program).** **There are important differences among the opioid overdose reversal agents, such as route of administration, product strength, approved patient age range, and pharmacokinetics. Be familiar with these differences, as outlined in the approved labeling for those products, prior to recommending or prescribing such an agent.** **Educate patients and caregivers on how to recognize respiratory depression, and how to use an opioid overdose reversal agent for the emergency treatment of opioid overdose. Emphasize the importance of calling 911 or getting emergency medical help, even if an opioid overdose reversal agent is administered *[see Dosage and Administration (2.x), Warnings and Precautions (5.x, 5.x), Overdosage (10)]*.**

	Precautions (5.x, 5.x), Overdosage (10)].	
	5.x Risks from Concomitant Use with Benzodiazepines or Other CNS Depressants Profound sedation, respiratory depression, coma, and death may result from concomitant use of [TRADENAME] with benzodiazepines and/or other CNS depressants, including alcohol (e.g., non-benzodiazepines, sedative/hypnotics, anxiolytics, tranquilizers, muscle relaxants, general anesthetics, antipsychotics, and other opioids). Because of these risks, reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. … If concomitant use is warranted, consider prescribing naloxone for the emergency treatment of opioid overdose *[see Dosage and Administration (2.x), Warnings and Precautions (5.x), Overdosage (10)]*.	**5.x Risks from Concomitant Use with Benzodiazepines or Other CNS Depressants** Profound sedation, respiratory depression, coma, and death may result from concomitant use of [TRADENAME] with benzodiazepines and/or other CNS depressants, including alcohol (e.g., non-benzodiazepines, sedative/hypnotics, anxiolytics, tranquilizers, muscle relaxants, general anesthetics, antipsychotics, **gabapentinoids**, and other opioids). Because of these risks, reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. … If concomitant use is warranted, consider prescribing ~~naloxone for the emergency treatment of~~ **an** opioid overdose **reversal agent** *[see Dosage and Administration (2.x), Warnings and Precautions (5.x), Overdosage (10)]*.
	5.x Risk of Use in Patients with Gastrointestinal Conditions [TRADENAME] is contraindicated in patients with known or suspected gastrointestinal obstruction, including paralytic ileus. The [drug] in [TRADENAME] may cause spasm of the sphincter of Oddi. Opioids may cause increases in serum amylase. Regularly evaluate patients with biliary tract disease, including pancreatitis, for worsening symptoms.	**5.x Risk of ~~Use in Patients with~~ Gastrointestinal ~~Conditions~~ Complications** [TRADENAME] is contraindicated in patients with known or suspected gastrointestinal obstruction, including paralytic ileus. The [drug] in [TRADENAME] may cause spasm of the sphincter of Oddi. Opioids may cause increases in serum amylase. Regularly evaluate patients with biliary tract disease, including pancreatitis, for worsening symptoms. **Cases of opioid-induced esophageal dysfunction (OIED) have been reported in patients taking opioids. The risk of OIED may increase as the dose and/or duration of opioids increases. Regularly evaluate patients for signs and symptoms of OIED (e.g., dysphagia, regurgitation, non-cardiac chest pain), and if necessary, adjust opioid therapy as clinically appropriate.**

6 ADVERSE REACTIONS	**6.X Postmarketing Experience** *(New section discussing PMR study results to be added)*	**6.X Postmarketing Experience** **Adverse Reactions from Observational Studies** **A prospective, observational cohort study estimated the risks of addiction, abuse, and misuse in patients initiating long-term use of Schedule II opioid analgesics between 2017 and 2021. Study participants included in one or more analyses had been enrolled in selected insurance plans or health systems for at least one year, were free of at least one outcome at baseline, completed a minimum number of follow-up assessments, and either 1) filled multiple extended-release/long-acting opioid analgesic prescriptions during a 90 day period (n=978); or 2) filled any Schedule II opioid analgesic for at least 70 of 90 days (n=1,244). Those included also had no dispensing of the qualifying opioids in the previous 6 months. Over 12 months:** • **approximately 1% to 6% of participants across the two cohorts newly met criteria for addiction, as assessed with two validated interview-based measures of moderate-to-severe opioid use disorder based on Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) criteria, and** • **approximately 9% and 22% of participants across the two cohorts newly met criteria for prescription opioid abuse and misuse [defined in Drug Abuse and Dependence (9.2)], respectively, as measured with a validated self-reported instrument.** **A retrospective, observational cohort study estimated the risk of opioid-involved overdose or opioid overdose-related death in patients with new long-term use of Schedule II opioid analgesics from 2006 through 2016 (n=220,249). Included patients had been enrolled in either one of two commercial insurance programs, one managed care program, or one Medicaid program for at least 9 months. New long-term use was defined as having Schedule II opioid analgesic prescriptions covering at least 70 days' supply over the 3 months prior to study entry and none during the preceding 6 months. Patients were excluded if they had an opioid-involved overdose in the 9 months prior to study entry. Overdose was measured using a validated medical code-based algorithm with linkage to the National Death Index database. The 5-year cumulative incidence estimates for opioid-involved overdose or opioid overdose-related death ranged from approximately 1.5% to 4% across study sites, counting only the first event during follow-up. Approximately 17% of first opioid overdoses observed over the entire study period (5-11 years, depending on the study site) were fatal. Higher baseline opioid dose was the strongest and most consistent predictor of opioid-involved overdose or opioid overdose-related death. Study exclusion criteria may have selected patients at lower risk of overdose, and substantial loss to follow-up (approximately 80%) also may have biased estimates.** **The risk estimates from the studies described above may not be generalizable to all patients receiving opioid analgesics, such as those with exposures shorter or longer than the duration evaluated in the studies.**

7 DRUG INTERACTIONS

Table X: Clinically Significant Drug Interactions with TRADENAME

Benzodiazepines and Other Central Nervous System (CNS) Depressants	
Clinical Impact:	Due to additive pharmacologic effect, the concomitant use of benzodiazepines or other CNS depressants, including alcohol, can increase the risk of hypotension, respiratory depression, profound sedation, coma, and death.
Intervention:	Reserve concomitant prescribing of these drugs for use in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients closely for signs of respiratory depression and sedation. If concomitant use is warranted, consider prescribing ~~naloxone for the emergency treatment of~~ **an** opioid overdose **reversal agent** *[see Dosage and Administration (2.x, 2.x), Warnings and Precautions (5.x, 5.x, 5.x)]*.
Examples:	Benzodiazepines and other sedatives/hypnotics, anxiolytics, tranquilizers, muscle relaxants, general anesthetics, antipsychotics, **gabapentinoids**, other opioids, alcohol.

Muscle Relaxants	
Clinical Impact:	[Drug] may enhance the neuromuscular blocking action of skeletal muscle relaxants and produce an increased degree of respiratory depression.
Intervention:	Monitor patients for signs of respiratory depression that may be greater than otherwise expected and decrease the dosage of [TRADENAME] and/or the muscle relaxant as necessary. Due to the risk of respiratory depression with concomitant use of skeletal muscle relaxants and opioids, consider prescribing ~~naloxone for the emergency treatment of~~ **an** opioid overdose **reversal agent** *[see Dosage and Administration (2.x), Warnings and Precautions (5.x, 5.x)]*
Examples:	cyclobenzaprine, metaxalone

8 USE IN SPECIFIC POPULATIONS

Clinical Considerations

Labor or Delivery

Opioids cross the placenta and may produce respiratory depression and psycho-physiologic effects in neonates. An opioid antagonist, such as naloxone, must be available for reversal of opioid-induced respiratory depression in the neonate.

Clinical Considerations

Labor or Delivery

Opioids cross the placenta and may produce respiratory depression and psycho-physiologic effects in neonates. An opioid ~~antagonist~~ **overdose reversal agent**, such as naloxone **or nalmefene**, must be available for reversal of opioid-induced respiratory depression in the neonate.

9 DRUG ABUSE AND DEPENDENCE

9.3 Dependence

Withdrawal may be precipitated through the administration of drugs with opioid antagonist activity (e.g., naloxone), mixed agonist/antagonist analgesics (e.g., pentazocine, butorphanol, nalbuphine), or partial agonists (e.g., buprenorphine). Physical dependence may not occur to a clinically significant degree until after several days to weeks of continued use.

9.3 Dependence

Withdrawal may be precipitated through the administration of drugs with opioid antagonist activity (e.g., naloxone, **nalmefene**), mixed agonist/antagonist analgesics (e.g., pentazocine, butorphanol, nalbuphine), or partial agonists (e.g., buprenorphine). Physical dependence may not occur to a clinically significant degree until after several days to weeks of continued use.

10 OVERDOSAGE

Clinical Presentation

Acute overdose with [TRADENAME] can be manifested by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, and in some cases, pulmonary edema, bradycardia, hypotension, hypoglycemia, partial or complete airway obstruction, atypical snoring, and death. Marked

Clinical Presentation

Acute overdose with [TRADENAME] can be manifested by respiratory depression, somnolence progressing to stupor or coma, skeletal muscle flaccidity, cold and clammy skin, constricted pupils, and in some cases, pulmonary edema, bradycardia, hypotension, hypoglycemia, partial or complete airway obstruction, atypical snoring, and death. Marked mydriasis rather than miosis may be seen with hypoxia in overdose situations *[see Clinical Pharmacology (12.2)]*. **Toxic**

	mydriasis rather than miosis may be seen with hypoxia in overdose situations *[see Clinical Pharmacology (12.2)]*. Treatment of Overdose The opioid antagonists, such as naloxone, are specific antidotes to respiratory depression resulting from opioid overdose. For clinically significant respiratory or circulatory depression secondary to opioid overdose, administer an opioid antagonist.	**leukoencephalopathy has been reported after opioid overdose and can present hours, days, or weeks after apparent recovery from the initial intoxication.** Treatment of Overdose ~~The opioid antagonists, such as naloxone, are specific antidotes to respiratory depression resulting from opioid overdose.~~ For clinically significant respiratory or circulatory depression secondary to opioid overdose, administer an opioid ~~antagonist~~ **overdose reversal agent such as naloxone or nalmefene**.
12 CLINICAL PHARMACOLOGY	**12.2 Pharmacodynamics** Effects on the Gastrointestinal Tract and Other Smooth Muscle Other opioid-induced effects may include a reduction in biliary and pancreatic secretions, spasm of sphincter of Oddi, and transient elevations in serum amylase.	**12.2 Pharmacodynamics** Effects on the Gastrointestinal Tract and Other Smooth Muscle Other opioid-induced effects may include a reduction in biliary and pancreatic secretions, spasm of sphincter of Oddi, ~~and~~ transient elevations in serum amylase**, and opioid-induced esophageal dysfunction (OIED).**
17 PATIENT COUNSELING INFORMATION	Patient Access to Naloxone for the Emergency Treatment of Opioid Overdose Discuss with the patient and caregiver the availability of naloxone for the emergency treatment of opioid overdose, both when initiating and renewing treatment with TRADENAME. Inform patients and caregivers about the various ways to obtain naloxone as permitted by individual state naloxone dispensing and prescribing requirements or guidelines (e.g., by prescription, directly from a pharmacist, or as part of a community-based program) *[see Dosage and Administration (2.x), Warnings and Precautions (5.x)]*. Educate patients and caregivers on how to recognize the signs and symptoms of an overdose. Explain to patients and caregivers that naloxone's effects are temporary, and that they must call 911 or get emergency medical help right away in all cases of known or suspected opioid overdose, even if naloxone is administered *[see Overdosage (10)]*. If naloxone is prescribed, also advise patients and caregivers: • How to treat with naloxone the overdose reversal agent in the event of an opioid overdose. • To tell family and friends about the naloxone opioid overdose reversal agent, and to keep it in a place where family and friends can access it in an emergency. • To read the Patient Information (or other educational material) that will come with their naloxone opioid overdose reversal agent. Emphasize the importance of doing this before an opioid emergency happens, so the patient and caregiver will know what to do.	Patient Access to ~~Naloxone~~ **an Opioid Overdose Reversal Agent** for the Emergency Treatment of Opioid Overdose ~~Discuss with the patient and caregiver the availability of naloxone for the emergency treatment of opioid overdose, both when initiating and renewing treatment with TRADENAME. Inform patients and caregivers about the various ways to obtain naloxone as permitted by individual state naloxone dispensing and prescribing requirements or guidelines (e.g., by prescription, directly from a pharmacist, or as part of a community-based program) *[see Dosage and Administration (2.x), Warnings and Precautions (5.x)]*.~~ **Inform patients and caregivers about opioid overdose reversal agents (e.g., naloxone, nalmefene). Discuss the importance of having access to an opioid overdose reversal agent, especially if the patient has risk factors for overdose (e.g., concomitant use of CNS depressants, a history of opioid use disorder, or prior opioid overdose) or if there are household members (including children) or other close contacts at risk for accidental ingestion or opioid overdose.** **Discuss with the patient the options for obtaining an opioid overdose reversal agent (e.g., prescription, over-the-counter, or as part of a community-based program) *[see Dosage and Administration (2.x), Warnings and Precautions (5.x)]*.** Educate patients and caregivers on how to recognize the signs and symptoms of an overdose. Explain to patients and caregivers that ~~naloxone's~~ effects **of opioid overdose reversal agents like naloxone and nalmefene** are temporary, and that they must call 911 or get emergency medical help right away in all cases of known or suspected opioid overdose, even if ~~naloxone~~ **an opioid overdose reversal agent** is administered *[see Overdosage (10)]*. ~~If naloxone is prescribed, also a~~**A**dvise patients and caregivers: • ~~H~~ **h**ow to treat with ~~naloxone~~ **the overdose reversal agent** in the event of an opioid overdose. • ~~T~~ **t**o tell family and friends about the ~~naloxone~~ **opioid overdose reversal agent,**

		and to keep it in a place where family and friends can access it in an emergency. • ~~T~~ **t**o read the Patient Information (or other educational material) that will come with their ~~naloxone~~ **opioid overdose reversal agent**. Emphasize the importance of doing this before an opioid emergency happens, so the patient and caregiver will know what to do.
MEDICATION GUIDE	**Important information about TRADENAME:** • **Get emergency help or call 911 right away if you take too much [TRADENAME] (overdose).** When you first start taking [TRADENAME], when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur. Talk to your healthcare provider about naloxone, a medicine for the emergency treatment of an opioid overdose. • Taking [TRADENAME] with other opioid medicines, benzodiazepines, gabapentinoids (gabapentin or pregabalin), alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.	**Important information about TRADENAME:** • **Get emergency help or call 911 right away if you take too much [TRADENAME] (overdose).** When you first start taking [TRADENAME], when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur. ~~Talk to~~ **Ask** your healthcare provider about **medicines like** naloxone **or nalmefene that can be used in an emergency to reverse an opioid overdose.**~~, a medicine for the emergency treatment of an opioid overdose.~~ • Taking [TRADENAME] with other opioid medicines, benzodiazepines, **gabapentinoids (gabapentin or pregabalin),** alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.