

March 22, 2016, Required Safety Labeling Language for Immediate-Release Opioids

The following mocked up labeling is an example of how the required safety labeling changes may be implemented and does not represent a complete package insert. This example is for a single-entity, solid oral dosage form. The language may vary for different products.

ADDICTION, ABUSE, AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME

Addiction, Abuse, and Misuse

[TRADENAME] exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing [TRADENAME], and monitor all patients regularly for the development of these behaviors or conditions [see *Warnings and Precautions (5.X)*].

Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of [TRADENAME]. Monitor for respiratory depression, especially during initiation of [TRADENAME] or following a dose increase [see *Warnings and Precautions (5.X)*].

Accidental Ingestion

Accidental ingestion of even one dose of [TRADENAME], especially by children, can result in a fatal overdose of [active moiety] [see *Warnings and Precautions (5.X)*].

Neonatal Opioid Withdrawal Syndrome

Prolonged use of [TRADENAME] during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available [see *Warnings and Precautions (5.X)*].

1 INDICATIONS AND USAGE

[TRADENAME] is indicated for the management of [*insert product-specific indication*] pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses [see *Warnings and Precautions (5.X)*], 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

2 DOSAGE AND ADMINISTRATION

2.1 Important Dosage and Administration Instructions

Initiate the dosing regimen for each patient individually, taking into account the patient's severity of pain, patient response, prior analgesic treatment experience, and risk factors for addiction, abuse, and misuse [*see Warnings and Precautions (5.X)*].

Monitor patients closely for respiratory depression, especially within the first 24-72 hours of initiating therapy and following dosage increases with [TRADENAME] and adjust the dosage accordingly [*see Warnings and Precautions (5.X)*].

2.2 Initial Dosage

Use of [TRADENAME] as the First Opioid Analgesic

Initiate treatment with [TRADENAME] in a dosing range of X to X mg every X to X hours as needed for pain.

Conversion from Other Opioids to [TRADENAME]

There is inter-patient variability in the potency of opioid drugs and opioid formulations. Therefore, a conservative approach is advised when determining the total daily dosage of [TRADENAME]. It is safer to underestimate a patient's 24-hour [TRADENAME] dosage than to overestimate the 24-hour [TRADENAME] dosage and manage an adverse reaction due to overdose.

Conversion from [TRADENAME] to Extended-Release [active moiety]

The relative bioavailability of [TRADENAME] compared to extended-release [active moiety] is unknown, so conversion to extended-release [dosage form] must be accompanied by close observation for signs of excessive sedation and respiratory depression.

2.X Titration and Maintenance of Therapy

Individually titrate [TRADENAME] to a dose that provides adequate analgesia and minimizes adverse reactions. Continually reevaluate patients receiving [TRADENAME] to assess the maintenance of pain control and the relative incidence of adverse reactions, as well as monitoring for the development of addiction, abuse, or misuse [*see Warnings and Precautions (5.X)*]. Frequent communication is important among the prescriber, other members of the healthcare team, the patient, and the caregiver/family during periods of changing analgesic requirements, including initial titration.

If the level of pain increases after dosage stabilization, attempt to identify the source of increased pain before increasing the [TRADENAME] dosage. If unacceptable opioid-related adverse reactions are observed, consider reducing the dosage. Adjust the dosage to obtain an appropriate balance between management of pain and opioid-related adverse reactions.

2.X Discontinuation of [TRADENAME]

When a patient who has been taking [TRADENAME] regularly and may be physically dependent no longer requires therapy with [TRADENAME], use a gradual downward titration of the dosage to prevent signs and symptoms of withdrawal. Do not stop [TRADENAME] abruptly [*see Warnings and Precautions (5.X), Drug Abuse and Dependence (9.3)*].

[TRADENAME] is contraindicated in patients with:

- Significant respiratory depression [*see Warnings and Precautions (5.X)*]
- Acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment [*see Warnings and Precautions (5.X)*]

5 WARNINGS AND PRECAUTIONS

5.X Addiction, Abuse, and Misuse

[TRADENAME] contains [active moiety], a Schedule [XX] controlled substance. As an opioid, [TRADENAME] exposes users to the risks of addiction, abuse, and misuse [*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.

Assess each patient's risk for opioid addiction, abuse, or misuse prior to prescribing [TRADENAME], and monitor all patients receiving [TRADENAME] for the development of these behaviors or conditions. Risks are increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness (e.g., major depression). The potential for these risks should not, however, prevent the proper management of pain in any given patient. Patients at increased risk may be prescribed opioids such as [TRADENAME], but use in such patients necessitates intensive counseling about the risks and proper use of [TRADENAME] along with intensive monitoring for signs of addiction, abuse, and misuse.

Opioids are sought by drug abusers and people with addiction disorders and are subject to criminal diversion. Consider these risks when prescribing or dispensing [TRADENAME]. Strategies to reduce these risks include prescribing the drug in the smallest appropriate quantity and advising the patient on the proper disposal of unused drug [*see Patient Counseling Information (17)*]. Contact local state professional licensing board or state controlled substances authority for information on how to prevent and detect abuse or diversion of this product.

5.X Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression has been reported with the use of opioids, even when used as recommended. Respiratory depression, if not immediately recognized and treated, may lead to respiratory arrest and death. Management of respiratory depression may include close observation, supportive measures, and use of opioid antagonists, depending on the patient's clinical status [*see Overdosage (10)*]. Carbon dioxide (CO₂) retention from opioid-induced respiratory depression can exacerbate the sedating effects of opioids.

While serious, life-threatening, or fatal respiratory depression can occur at any time during the use of [TRADENAME], the risk is greatest during the initiation of therapy or following a dosage increase. Monitor patients closely for respiratory depression, especially within the first 24-72 hours of initiating therapy with and following dosage increases of [TRADENAME].

To reduce the risk of respiratory depression, proper dosing and titration of [TRADENAME] are essential [*see Dosage and Administration (2.X)*]. Overestimating the [TRADENAME] dosage when converting patients from another opioid product can result in a fatal overdose with the first dose.

Accidental ingestion of even one dose of [TRADENAME], especially by children, can result in respiratory depression and death due to an overdose of [active moiety].

5.X Neonatal Opioid Withdrawal Syndrome

Prolonged use of [TRADENAME] during pregnancy can result in withdrawal in the neonate. Neonatal opioid withdrawal syndrome, unlike opioid withdrawal syndrome in adults, may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available [*see Use in Specific Populations (8.1), Patient Counseling Information*].

5.X Risks due to Interactions with Central Nervous System Depressants

Hypotension, profound sedation, respiratory depression, coma, and death may result if [TRADENAME] is used concomitantly with alcohol or other central nervous system (CNS) depressants (e.g., benzodiazepines and other sedatives/hypnotics, anxiolytics, tranquilizers, muscle relaxants, general anesthetics, antipsychotics, and other opioids).

When considering the use of [TRADENAME] in a patient taking a CNS depressant, assess the duration of use of the CNS depressant and the patient's response, including the degree of tolerance that has developed to CNS depression. Additionally, evaluate the patient's use of alcohol or illicit drugs that can cause CNS depression. If the decision to begin [TRADENAME] is made, start with a lower dosage of [TRADENAME], monitor patients for signs of respiratory depression, sedation, and hypotension, and consider using a lower dose of the concomitant CNS depressant. [*see Drug Interactions (7)*].

5.X Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients

The use of [TRADENAME] in patients with acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment is contraindicated.

Patients with Chronic Pulmonary Disease: [TRADENAME]-treated patients with significant chronic obstructive pulmonary disease or cor pulmonale, and those with a substantially decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression are at increased risk of decreased respiratory drive including apnea, even at recommended dosages of [TRADENAME] [*see Warnings and Precautions (5.X)*].

Elderly, Cachectic, or Debilitated Patients: Life-threatening respiratory depression is more likely to occur in elderly, cachectic, or debilitated patients because they may have altered pharmacokinetics or altered clearance compared to younger, healthier patients [*see Warnings and Precautions (5.X)*].

Monitor such patients closely, particularly when initiating and titrating [TRADENAME] and when [TRADENAME] is given concomitantly with other drugs that depress respiration [*see Warnings and Precautions (5.X)*]. Alternatively, consider the use of non-opioid analgesics in these patients.

5.X Adrenal Insufficiency

Cases of adrenal insufficiency have been reported with opioid use, more often following greater than one month of use. Presentation of adrenal insufficiency may include non-specific symptoms and signs including nausea, vomiting, anorexia, fatigue, weakness, dizziness, and low blood pressure. If adrenal insufficiency is suspected, confirm the diagnosis with diagnostic testing as soon as possible. If adrenal insufficiency is diagnosed, treat with physiologic replacement doses of corticosteroids. Wean the patient off of the opioid to allow adrenal function to recover and continue corticosteroid treatment until adrenal function recovers. Other opioids may be tried as some cases reported use of a different opioid without recurrence of adrenal insufficiency. The information available does not identify any particular opioids as being more likely to be associated with adrenal insufficiency.

6 ADVERSE REACTIONS

The following serious adverse reactions are described, or described in greater detail, in other sections:

- Addiction, Abuse, and Misuse [see Warnings and Precautions (5.X)]
- Life-Threatening Respiratory Depression [see Warnings and Precautions (5.X)]
- Neonatal Opioid Withdrawal Syndrome [see Warnings and Precautions (5.X)]
- Interactions with CNS Depressants [see Warnings and Precautions (5.X)]
- Adrenal Insufficiency [see Warnings and Precautions (5.X)]

6.2 Postmarketing Experience

serotonin syndrome, adrenal insufficiency

Androgen deficiency: Chronic use of opioids may influence the hypothalamic-pituitary-gonadal axis, leading to androgen deficiency that may manifest as low libido, impotence, erectile dysfunction, amenorrhea, or infertility. The causal role of opioids in the clinical syndrome of hypogonadism is unknown because the various medical, physical, lifestyle, and psychological stressors that may influence gonadal hormone levels have not been adequately controlled for in studies conducted to date. Patients presenting with symptoms of androgen deficiency should undergo laboratory evaluation.

7 DRUG INTERACTIONS

Table X includes clinically significant drug interactions with [TRADENAME].
(In the table below, include relevant cross-references to section 12)

Table X: Clinically Significant Drug Interactions with [TRADENAME]

Central Nervous System (CNS) Depressants	
<i>Clinical Impact:</i>	Due to additive pharmacologic effect, the concomitant use of CNS depressants can increase the risk of hypotension, respiratory depression, profound sedation, coma, and death.
<i>Intervention:</i>	Consider dose reduction of one or both drugs. Monitor patients for signs of respiratory depression, sedation, and hypotension [see Warnings and Precautions (5.X)].
<i>Examples:</i>	Alcohol, benzodiazepines and other sedatives/hypnotics, anxiolytics, tranquilizers, muscle relaxants, general anesthetics, antipsychotics, other opioids.
Serotonergic Drugs	
<i>Clinical Impact:</i>	The concomitant use of opioids with other drugs that affect the serotonergic neurotransmitter system has resulted in serotonin syndrome.
<i>Intervention:</i>	If concomitant use is warranted, carefully observe the patient, particularly during treatment initiation and dose adjustment. Discontinue [TRADENAME] if serotonin syndrome is suspected.
<i>Examples:</i>	Selective serotonin reuptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), triptans, 5-HT ₃ receptor antagonists, drugs that effect the serotonin neurotransmitter system (e.g., mirtazapine, trazodone, tramadol), monoamine oxidase (MAO) inhibitors (those intended to treat psychiatric disorders and also others, such as linezolid and intravenous methylene blue).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Prolonged use of opioid analgesics during pregnancy may cause neonatal opioid withdrawal syndrome.

Clinical Considerations

Fetal/Neonatal Adverse Reactions

Prolonged use of opioid analgesics during pregnancy for medical or nonmedical purposes can result in physical dependence in the neonate and neonatal opioid withdrawal syndrome shortly after birth.

Neonatal opioid withdrawal syndrome presents as irritability, hyperactivity and abnormal sleep pattern, high pitched cry, tremor, vomiting, diarrhea and failure to gain weight. The onset, duration, and severity of neonatal opioid withdrawal syndrome vary based on the specific opioid used, duration of use, timing and amount of last maternal use, and rate of elimination of the drug by the newborn. Observe newborns for symptoms of neonatal opioid withdrawal syndrome and manage accordingly [*see Warnings and Precautions (5.X)*].

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. [TRADENAME] is not recommended for use in pregnant women during or immediately prior to labor, when other analgesic techniques are more appropriate. Opioid analgesics, including [TRADENAME], can prolong labor through actions which temporarily reduce the strength, duration, and frequency of uterine contractions. However, this effect is not consistent and may be offset by an increased rate of cervical dilation, which tends to shorten labor. Monitor neonates exposed to opioid analgesics during labor for signs of excess sedation and respiratory depression.

8.2 Lactation

Risk Summary

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for [TRADENAME] and any potential adverse effects on the breastfed infant from [TRADENAME] or from the underlying maternal condition.

Clinical Considerations

Infants exposed to [TRADENAME] through breast milk should be monitored for excess sedation and respiratory depression. Withdrawal symptoms can occur in breastfed infants when maternal administration of an opioid analgesic is stopped, or when breast-feeding is stopped.

8.3 Females and Males of Reproductive Potential

Infertility

Chronic use of opioids may cause reduced fertility in females and males of reproductive potential. It is not known whether these effects on fertility are reversible [*see Adverse Reactions (6.2)*].

8.5 Geriatric Use

(Include drug-specific information regarding exposure to patients greater than 65 years old in your controlled trials. Describe any age-related differences in adverse reactions, if there were adequate number of elderly

exposed. If no data are available, include the following paragraph.)

(If no product-specific info is available, include the following) Elderly patients (aged 65 years or older) may have increased sensitivity to [active moiety]. In general, use caution when selecting a dosage for an elderly patient, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy.

Respiratory depression is the chief risk for elderly patients treated with opioids, and has occurred after large initial doses were administered to patients who were not opioid-tolerant or when opioids were co-administered with other agents that depress respiration. Titrate the dosage of [TRADENAME] slowly in geriatric patients [*see Warnings and Precautions (5.X)*].

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

[TRADENAME] contains [active moiety], a Schedule XX controlled substance.

9.2 Abuse

[TRADENAME] contains [active moiety], a substance with a high potential for abuse similar to other opioids including (*list active moieties other than your active moiety with similar abuse liability*). [TRADENAME] can be abused and is subject to misuse, addiction, and criminal diversion [*see Warnings and Precautions (5.X)*].

All patients treated with opioids require careful monitoring for signs of abuse and addiction, since use of opioid analgesic products carries the risk of addiction even under appropriate medical use.

Prescription drug abuse is the intentional non-therapeutic use of a prescription drug, even once, for its rewarding psychological or physiological effects.

Drug addiction is a cluster of behavioral, cognitive, and physiological phenomena that develop after repeated substance use and includes: a strong desire to take the drug, difficulties in controlling its use, persisting in its use despite harmful consequences, a higher priority given to drug use than to other activities and obligations, increased tolerance, and sometimes a physical withdrawal.

“Drug-seeking” behavior is very common in persons with substance use disorders. Drug-seeking tactics include emergency calls or visits near the end of office hours, refusal to undergo appropriate examination, testing, or referral, repeated “loss” of prescriptions, tampering with prescriptions and reluctance to provide prior medical records or contact information for other treating health care provider(s). “Doctor shopping” (visiting multiple prescribers) to obtain additional prescriptions is common among drug abusers and people suffering from untreated addiction. Preoccupation with achieving adequate pain relief can be appropriate behavior in a patient with poor pain control.

Abuse and addiction are separate and distinct from physical dependence and tolerance. Health care providers should be aware that addiction may not be accompanied by concurrent tolerance and symptoms of physical dependence in all addicts. In addition, abuse of opioids can occur in the absence of true addiction.

[TRADENAME], like other opioids, can be diverted for non-medical use into illicit channels of distribution. Careful record-keeping of prescribing information, including quantity, frequency, and renewal requests, as required by state and federal law, is strongly advised.

Proper assessment of the patient, proper prescribing practices, periodic re-evaluation of therapy, and proper dispensing and storage are appropriate measures that help to limit abuse of opioid drugs.

Risks Specific to Abuse of [TRADENAME]

(include information specific to TRADENAME)

9.3 Dependence

Both tolerance and physical dependence can develop during chronic opioid therapy. Tolerance is the need for increasing doses of opioids to maintain a defined effect such as analgesia (in the absence of disease progression or other external factors). Tolerance may occur to both the desired and undesired effects of drugs, and may develop at different rates for different effects.

Physical dependence results in withdrawal symptoms after abrupt discontinuation or a significant dosage reduction of a drug. Withdrawal also may be precipitated through the administration of drugs with opioid antagonist activity (e.g., naloxone, nalmefene), mixed agonist/antagonist analgesics (pentazocine, butorphanol, nalbuphine), or partial agonists (buprenorphine). Physical dependence may not occur to a clinically significant degree until after several days to weeks of continued opioid usage.

[TRADENAME] should not be abruptly discontinued [*see Dosage and Administration (2.X)*]. If [TRADENAME] is abruptly discontinued in a physically-dependent patient, a withdrawal syndrome may occur. Some or all of the following can characterize this syndrome: restlessness, lacrimation, rhinorrhea, yawning, perspiration, chills, myalgia, and mydriasis. Other signs and symptoms also may develop, including: irritability, anxiety, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, anorexia, vomiting, diarrhea, or increased blood pressure, respiratory rate, or heart rate.

Infants born to mothers physically dependent on opioids will also be physically dependent and may exhibit respiratory difficulties and withdrawal signs [*see Use in Specific Populations (8.1)*].

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, 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)*].

Treatment of Overdose

In case of overdose, priorities are the reestablishment of a patent and protected airway and institution of assisted or controlled ventilation, if needed. Employ other supportive measures (including oxygen and vasopressors) in the management of circulatory shock and pulmonary edema as indicated. Cardiac arrest or arrhythmias will require advanced life-support techniques.

The opioid antagonists, naloxone or nalmefene, are specific antidotes to respiratory depression resulting from opioid overdose. For clinically significant respiratory or circulatory depression secondary to [active moiety] overdose, administer an opioid antagonist. Opioid antagonists should not be administered in the absence of clinically significant respiratory or circulatory depression secondary to [active moiety] overdose.

Because the duration of opioid reversal is expected to be less than the duration of action of [active moiety] in [TRADENAME], carefully monitor the patient until spontaneous respiration is reliably re-established. If the response to an opioid antagonist is suboptimal or only brief in nature, administer additional antagonist as directed by the product's prescribing information.

17 PATIENT COUNSELING INFORMATION

Addiction, Abuse, and Misuse

Inform patients that the use of [TRADENAME], even when taken as recommended, can result in addiction, abuse, and misuse, which can lead to overdose and death [see *Warnings and Precautions (5.X)*]. Instruct patients not to share [TRADENAME] with others and to take steps to protect [TRADENAME] from theft or misuse.

Life-Threatening Respiratory Depression

Inform patients of the risk of life-threatening respiratory depression, including information that the risk is greatest when starting [TRADENAME] or when the dosage is increased, and that it can occur even at recommended dosages [see *Warnings and Precautions (5.X)*]. Advise patients how to recognize respiratory depression and to seek medical attention if breathing difficulties develop.

Accidental Ingestion

Inform patients that accidental ingestion (or exposure), especially by children, may result in respiratory depression or death [see *Warnings and Precautions (5.X)*]. Instruct patients to take steps to store [TRADENAME] securely and to dispose of unused [TRADENAME] by [insert product-specific disposal information].

Interactions with Alcohol and Other CNS Depressants

Inform patients that potentially serious additive effects may occur if [TRADENAME] is used with alcohol or other CNS depressants and not to use such drugs unless supervised by a health care provider [see *Warnings and Precautions (5.X), Drug Interactions (7)*].

Serotonin Syndrome

Inform patients that [TRADENAME] could cause a rare but potentially life-threatening condition resulting from concomitant administration of serotonergic drugs. Warn patients of the symptoms of serotonin syndrome and to seek medical attention right away if symptoms develop. Instruct patients to inform their physicians if they are taking, or plan to take serotonergic medications. [see *Drug Interactions 7*].

Adrenal Insufficiency

Inform patients that [TRADENAME] could cause adrenal insufficiency, a potentially life-threatening condition. Adrenal insufficiency may present with non-specific symptoms and signs such as nausea, vomiting, anorexia, fatigue, weakness, dizziness, and low blood pressure. Advise patients to seek medical attention if they experience a constellation of these symptoms [see *Warnings and Precautions (5.X)*].

Pregnancy

Neonatal Opioid Withdrawal Syndrome

Inform patients that prolonged use of [TRADENAME] during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated [see *Warnings and Precautions (5.x), Use in Specific Populations (8.1)*].

Embryo-Fetal Toxicity

Inform female patients of reproductive potential that [TRADENAME] can (or may) cause fetal harm and to inform the prescriber of a known or suspected pregnancy [see *Use in Specific Populations (8.1)*].

Lactation

Advise nursing mothers to monitor infants for increased sleepiness (more than usual), breathing difficulties, or limpness. Instruct nursing mothers to seek immediate medical care if they notice these signs [*see Use in Specific Populations (8.2)*].

Disposal of Unused [TRADENAME]

Advise patients to [insert product-specific disposal information].

Medication Guide

**[TRADENAME] ([insert phonetic spelling])
([insert established name]) [insert dosage form] , CXX**

[TRADENAME] is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage [insert indication], when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.

Important information about [TRADENAME]:

- **Get emergency help 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.
- Never give anyone else your [TRADENAME]. They could die from taking it. Store [TRADENAME] away from children and in a safe place to prevent stealing or abuse. Selling or giving away [TRADENAME] is against the law.

Do not take TRADENAME if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.
- [insert other product-specific information in order of importance]

Before taking TRADENAME, tell your healthcare provider if you have a history of:

- head injury, seizures
- problems urinating
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.
- liver, kidney, thyroid problems
- pancreas or gallbladder problems

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of [TRADENAME] during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** [TRADENAME] passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking [TRADENAME] with certain other medicines can cause serious side effects that could lead to death.

When taking TRADENAME:

- Do not change your dose. Take [TRADENAME] exactly as prescribed by your healthcare provider.
- Take your prescribed dose [insert frequency, e.g., every X hours at the same time every day]. Do not take more than your prescribed dose. If you miss a dose, take your next dose at your usual time.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking [TRADENAME] regularly, do not stop taking [TRADENAME] without talking to your healthcare provider.
- After you stop taking [TRADENAME], [insert product-specific disposal information].

While taking TRADENAME DO NOT:

- Drive or operate heavy machinery, until you know how [TRADENAME] affects you. [TRADENAME] can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with [TRADENAME] may cause you to overdose and die.

The possible side effects of TRADENAME:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

These are not all the possible side effects of [TRADENAME]. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

Manufactured by: [Insert name and address] and/or Distributed by: [Insert name and address], [www.\[TRADENAME\].com](http://www.[TRADENAME].com) or call 1-800-XXX-XXXX

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Issued: month/year