

Brightside Specialty Pharmacy

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Patient Education for OXYCONTIN ER 30 MG TABLET



May be habit forming. Avoid taking with other CNS depressant drugs or alcohol. Many drug-drug interactions possible with this drug. Dispense Medication Guide and explain to patient before use. May cause drowsiness or dizziness. Use caution driving. Taking more than recommended dose may cause respiratory arrest. Swallow whole. Do not break, chew, crush, or dissolve. High doses of this opiate can harm opiate-naïve users.

May be habit forming. Avoid alcohol/other drugs that make you sleepy. Review all drugs you are taking with your doctor. Before use, important to read the Medication Guide. May make you drowsy or dizzy. Drive with caution. Taking a larger dose may cause breathing problems. Swallow whole. Do not break/chew/crush/dissolve. May cause toxic effect in non-opiate using patients.

.....Education Section.....

IMPORTANT:

HOW TO USE THIS INFORMATION: This is a summary and

does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

OXYCODONE EXTENDED-RELEASE - ORAL

(ox-ee-KOH-doan)

COMMON BRAND NAME(S):

Oxycontin

WARNING:

Oxycodone has a risk for abuse and addiction, which can

lead to overdose and death. Oxycodone may also cause severe, possibly fatal, breathing problems. To lower your risk, your doctor should have you take the smallest dose of oxycodone that works, and take it for the shortest possible time. See also How to Use section for more information about addiction.

Ask your doctor or pharmacist if you should have naloxone available to treat opioid overdose. Teach your family or household members about the signs of an opioid overdose and how to treat it.

The risk for severe breathing problems is higher when you start this medication and after a dose increase, or if you take the wrong dose/strength. Taking this medication with alcohol or other drugs that can cause drowsiness or breathing problems may cause very serious side effects, including death. Also, other medications can affect the removal of oxycodone from your body, which may affect how oxycodone works. Be sure you know how to take oxycodone and what other drugs you should avoid taking with it. See also Drug Interactions section. Get medical help right away if any of these very serious side effects occur:

slow/shallow breathing, unusual lightheadedness, severe drowsiness/dizziness, difficulty waking up.

Do not break, crush, chew, or dissolve this medication. Taking

broken, crushed, chewed, or dissolved extended-release oxycodone could cause a fatal overdose.

Keep this medicine in a safe place to prevent theft, misuse, or abuse. If someone accidentally swallows this drug, get medical help right away.

Before using this medication, women of childbearing age should talk with their doctor(s) about the risks and benefits. Tell your doctor if you are pregnant or if you plan to become pregnant. During pregnancy, this medication should be used only when clearly needed. It may slightly increase the risk of birth defects if used during the first two months of pregnancy. Also, using it for a long time or in high doses near the expected delivery date may harm the unborn baby. To lessen the risk, take the smallest effective dose for the shortest possible time. Babies born to mothers who use this drug for a long time may develop severe (possibly fatal) withdrawal symptoms. Tell the doctor right away if you notice any symptoms in your newborn baby such as crying that doesn't stop, slow/shallow breathing, irritability, shaking, vomiting, diarrhea, poor feeding, or difficulty gaining weight.

USES:

This medication is used to help relieve severe ongoing

pain (such as due to cancer). Oxycodone belongs to a class of drugs known as opioid analgesics. It works in the brain to change how your body feels and responds to pain.

The higher strengths of this drug (more than 40 milligrams per tablet) should be used only if you have been regularly taking moderate to large amounts of an opioid pain medication. These strengths may cause overdose (even death) if taken by a person who has not been regularly taking opioids.

Do not use the extended-release form of oxycodone to relieve pain that is mild or that will go away in a few days. This medication is not for occasional ("as needed") use.

HOW TO USE:

See also Warning section.

Read the Medication Guide provided by your pharmacist before you start taking extended-release oxycodone and each time you get a refill. If you have any questions, ask your doctor or

pharmacist.

Take this medication on a regular schedule as directed by your doctor, not as needed for sudden (breakthrough) pain. Take this drug with or without food, usually every 12 hours. If you have nausea, it may help to take this drug with food. Ask your doctor or pharmacist about other ways to decrease nausea (such as lying down for 1 to 2 hours with as little head movement as possible). If nausea lasts, see your doctor.

Swallow the tablets whole. Do not break, crush, chew, or dissolve the tablets. Doing so can release all of the drug at once, increasing the risk of oxycodone overdose.

To lessen the chance of choking or having trouble swallowing the tablet, take only one a tablet at a time if your dose is for more than one tablet. Do not pre-soak, lick, or wet the tablet before placing it in your mouth. Be sure to drink enough water with each tablet to swallow it completely.

Avoid eating grapefruit or drinking grapefruit juice while using this medication unless your doctor or pharmacist says you may do so safely. Grapefruit can increase the chance of side effects with this medicine. Ask your doctor or pharmacist for more details.

The dosage is based on your medical condition and response to treatment. Do not increase your dose, take the medication more frequently, or take it for a longer time than prescribed. Properly stop the medication when so directed.

Before you start taking this medication, ask your doctor or pharmacist if you should stop or change how you use your other opioid medication(s). Other pain relievers (such as acetaminophen, ibuprofen) may also be prescribed. Ask your doctor or pharmacist about using oxycodone safely with other drugs.

Suddenly stopping this medication may cause withdrawal, especially if you have used it for a long time or in high doses. To prevent withdrawal, your doctor may lower your dose slowly. Tell your doctor or pharmacist right away if you have any withdrawal symptoms such as restlessness, mental/mood changes (including anxiety, trouble sleeping, thoughts of suicide), watering eyes, runny nose, nausea, diarrhea, sweating, muscle aches, or sudden changes in behavior.

When this medication is used for a long time, it may not work as well. Talk with your doctor if this medication stops working well.

Though it helps many people, this medication may sometimes cause addiction. This risk may be higher if you have a substance use disorder (such as overuse of or addiction to drugs/alcohol). Take this medication exactly as prescribed to lower the risk of addiction. Ask your doctor or pharmacist for more details.

Tell your doctor if your pain does not get better or if it gets worse.

SIDE EFFECTS:

See also Warning section.

Nausea, vomiting, constipation, dry mouth, weakness, sweating, lightheadedness, dizziness, or drowsiness may occur. Some of these side effects may decrease after you have been using this medication for a while. If any of these effects last or get worse, tell your doctor or pharmacist promptly.

To prevent constipation, eat dietary fiber, drink enough

water, and exercise. You may also need to take a laxative. Ask your pharmacist which type of laxative is right for you.

To reduce the risk of dizziness and lightheadedness, get up slowly when rising from a sitting or lying position.

You may notice an empty tablet shell in your stool. This is harmless because your body has already absorbed the medicine.

Remember that this medication has been prescribed because your doctor has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects.

Tell your doctor right away if you have any serious side effects, including: interrupted breathing during sleep (sleep apnea), mental/mood changes (such as agitation, confusion, hallucinations), severe stomach/abdominal pain, difficulty urinating, signs of your adrenal glands not working well (such as loss of appetite, unusual tiredness, weight loss).

Get medical help right away if you have any very serious side effects, including: fainting, seizure, slow/shallow breathing, severe drowsiness/difficulty waking up.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your doctor or pharmacist.

In the US -

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch.

In Canada - Call your doctor for medical advice about side effects. You may report side effects to Health Canada at 1-866-234-2345.

PRECAUTIONS:

Before taking oxycodone, tell your doctor or

pharmacist if you are allergic to it; or to other opioid pain relievers (such as oxymorphone); or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: brain disorders (such as head injury, tumor, seizures), breathing problems (such as asthma, sleep apnea, chronic obstructive pulmonary disease-COPD), kidney disease, liver disease, mental/mood disorders (such as confusion, depression), personal or family history of a substance use disorder (such as overuse of or addiction to drugs/alcohol), stomach/intestinal problems (such as blockage, constipation, diarrhea due to infection, paralytic ileus), difficulty swallowing, difficulty urinating (such as due to enlarged prostate), disease of the pancreas (pancreatitis), gallbladder disease.

This drug may make you dizzy or drowsy. Alcohol or marijuana (cannabis) can make you more dizzy or drowsy. Do not drive, use machinery, or do anything that needs alertness until you can do

it safely. Avoid alcoholic beverages. Talk to your doctor if you are using marijuana (cannabis).

Before having surgery, tell your doctor or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

Older adults may be more sensitive to the side effects of this drug, especially confusion, dizziness, drowsiness, and slow/shallow breathing.

During pregnancy, this medication should be used only when clearly needed. It may harm an unborn baby. Discuss the risks and benefits with your doctor. (See also Warning section.)

This drug passes into breast milk and may have undesirable effects on a nursing infant. Tell the doctor right away if your baby develops unusual sleepiness, difficulty feeding, or trouble breathing. Consult your doctor before breast-feeding.

DRUG INTERACTIONS:

See also Warning and How to Use sections.

Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your doctor and pharmacist. Do not start, stop, or change the dosage of any medicines without your doctor's approval.

Some products that may interact with this drug include: certain pain medications (mixed opioid agonist/antagonists such as butorphanol, nalbuphine, pentazocine), naltrexone, samidorphan.

The risk of serious side effects (such as slow/shallow breathing, severe drowsiness/dizziness) may be increased if this medication is taken with other products that may also cause drowsiness or breathing problems. Tell your doctor or pharmacist if you are taking other products such as other opioid pain or cough relievers (such as codeine, hydrocodone), alcohol, marijuana (cannabis), drugs for sleep or anxiety (such as alprazolam, lorazepam, zolpidem), muscle relaxants (such as carisoprodol, cyclobenzaprine), or antihistamines (such as cetirizine, diphenhydramine).

Check the labels on all your medicines (such as allergy or cough-and-cold products) because they may contain ingredients that cause drowsiness. Ask your pharmacist about using those products safely.

Other medications can affect the removal of oxycodone from your body, which may affect how oxycodone works. Examples include azole antifungals (such as ketoconazole), macrolide antibiotics (such as erythromycin), mifepristone, HIV medications (such as ritonavir), rifamycins (such as rifabutin, rifampin), certain drugs used to treat seizures (such as carbamazepine, phenytoin), among others.

This medication may interfere with certain laboratory tests (including amylase/lipase levels), possibly causing false test results. Make sure laboratory personnel and all your doctors know you use this drug.

OVERDOSE:

If someone has overdosed and has serious symptoms such

as passing out or trouble breathing, give them naloxone if available, then call 911. If the person is awake and has no symptoms, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Canada residents can call a provincial poison control center.

Symptoms of overdose may include:

slow/shallow breathing, slow

heartbeat, coma.

NOTES:

Do not share this medication with others. Sharing it is

against the law.

This medication has been prescribed for your current condition only. Do not use it later for another condition unless told to do so by your doctor. A different medication may be necessary in that case.

MISSED DOSE:

If you miss a dose, skip the missed dose. Take your

next dose at the regular time. Do not double the dose to catch up.

STORAGE:

Store at room temperature away from light and moisture.

Do not store in the bathroom. Keep all medications away from children and pets. See also Warning section.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. For more details, read the Medication Guide, or consult your pharmacist or local waste disposal company.

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