



Oxycodone Safety Handout For Patients

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Patient Education – An Absolute Safety Necessity

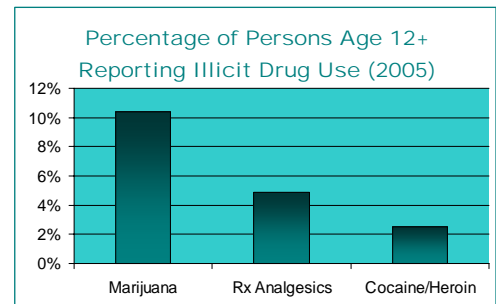
Most patients and their families or caregivers find the medication information provided by pharmacies, or product package inserts (if provided), difficult to read and understand. Hence, they are of little help as a safety measure.

Opioid medications must especially be safeguarded by patients. Recent data suggest that teenage pilferage and illicit use of prescription opioids from their parents' medicine cabinets is a continuing and growing problem (CSS 2006). The latest U.S. household survey found that the nonmedical, illicit use of prescription pain relievers was second only to marijuana abuse and exceeded the abuse of any other illicit substance (CESAR 2006a). It was twice that of cocaine and heroin use combined (see **Graph**). In all, approximately 7.25 million persons age 12 and older used prescription pain relievers for nonmedical purposes in 2005 and the alarming trend was rising.



Furthermore, opioid analgesics are more likely than such agents as cocaine or heroin to be the cause of unintentional drug-poisoning fatalities in the U.S. An analysis of data from 2002, showed that opioid analgesics accounted for more than a third (36.5%) of drug-poisoning deaths (CESAR 2006b).

In the drug-poisoning data, it is not known how many deaths involved *illicit nonmedical opioid use* (eg, recreational) versus those resulting from *medical misuse* (eg, noncompliance with the prescribed dosing regimen or mixing with other medications), or from *misprescribing*. It seems logical that better patient education regarding therapeutic compliance might help prevent unintentional medical misuse of oxycodone, and better safety precautions could help avoid oxycodone from falling into the hands of persons who might use the drug for illicit, nonmedical purposes.



Yet, a recent observational study found that busy healthcare providers often failed to adequately instruct patients and communicate critical information regarding various prescribed medications (Tarn et al. 2006). This might expectedly contribute to misunderstandings by patients leading to noncompliance and/or medication misuse, which could be harmful or fatal in the case of opioids.

About the Patient Oxycodone Instructions Handouts (attached)

To assist healthcare providers in their vital patient-education responsibilities, *Pain Treatment Topics* developed the special "Patient Instructions" handouts on the pages that follow this introduction. These can be reproduced and given to patients at the time oxycodone analgesia

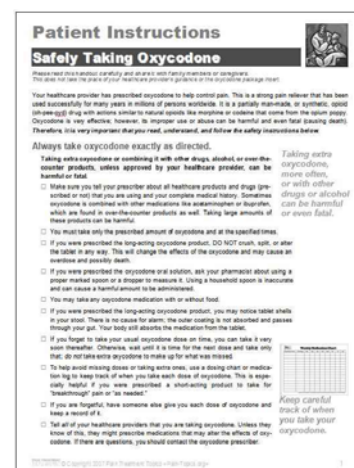
is prescribed (see *permission to reproduce below*). Ideally, these also would be used as discussion guides for face-to-face education of patients – and their families or caregivers.

The emphasis of the handouts is on **safety**, to help prevent misuse and avoidable adverse events potentially associated with oxycodone. They do not necessarily include *all* information in oxycodone product package inserts or provided by medical staff, and are not intended to take the place of such guidance. However, unlike traditional communications of this sort, the handouts stress several points that often are overlooked:

- Patients (along with their families or caregivers) must be specifically cautioned that oxycodone can be fatal if it is misused.
- As a strong opioid agent, absolute compliance with the prescribed oxycodone regimen is essential; unauthorized extra doses should never be taken.
- Patients must keep careful track of when they take oxycodone, enlisting the help of others in this if necessary.
- Patients need to understand the importance of reporting all substances that they are using – medications, drugstore products, alcohol, or other drugs – and that unauthorized use of these with oxycodone can be harmful or even fatal.
- Oxycodone must be safeguarded from theft and illicit use by others. It should not be casually stored as many other medications might be.
- Family members or caregivers must know of oxycodone overdose warning signs and be instructed to seek emergency help if any occur.
- Patients' fears of opioid addiction should be dispelled. Along with that, they must be cautioned against reducing oxycodone dosing on their own.

The handouts provide more detail regarding these essential messages and very specific recommendations. It is hoped that healthcare providers will take the extra time necessary for providing such information and instructions that can help promote the effective and safe use of oxycodone analgesia.

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Further Information for Healthcare Providers

The following document from *Pain Treatment Topics* has vital supplemental information for healthcare providers on how oxycodone works and its safe prescribing. This paper should be reviewed prior to distributing the *Safely Taking Oxycodone* patient instructions handout.

Commonsense Oxycodone Prescribing & Safety

Lee A. Kral, PharmD, BCPS, June 2007.

Get PDF at: <http://www.pain-topics.org/pdf/OxycodoneRxSafety.pdf>
(310 KB; 18 pp).



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Medical reviewers:

The qualifications of *Pain Treatment Topics* medical advisors/reviewers for this document may be viewed at: http://www.pain-topics.org/contacts_aboutus/index.php#MedAdvisors.

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Patient Instructions

Safely Taking Oxycodone



Please read this handout carefully and share it with family members or caregivers.

This does not take the place of your healthcare provider's guidance or the oxycodone package insert.

Your healthcare provider has prescribed oxycodone to help control pain. This is a strong pain reliever that has been used successfully for many years in millions of persons worldwide. It is a partially man-made, or synthetic, opioid (oh-pee-oyd) drug with actions similar to natural opioids like morphine or codeine that come from the opium poppy. Oxycodone is very effective; however, its improper use or abuse can be harmful and even fatal (causing death).

Therefore, it is very important that you read, understand, and follow the safety instructions below.

Always take oxycodone exactly as directed.

Taking extra oxycodone or combining it with other drugs, alcohol, or over-the-counter products, unless approved by your healthcare provider, can be harmful or fatal.

- Make sure you tell your prescriber about all healthcare products and drugs (prescribed or not) that you are using and your complete medical history. Sometimes oxycodone is combined with other medications like acetaminophen or ibuprofen, which are found in over-the-counter products as well. Taking large amounts of these products can be harmful.
- You must take only the prescribed amount of oxycodone and at the specified times.
- If you were prescribed the long-acting oxycodone product, DO NOT crush, split, or alter the tablet in any way. This will change the effects of the oxycodone and may cause an overdose and possibly death.
- If you were prescribed the oxycodone oral solution, ask your pharmacist about using a proper marked spoon or a dropper to measure it. Using a household spoon is inaccurate and can cause a harmful amount to be administered.
- You may take any oxycodone medication with or without food.
- If you were prescribed the long-acting oxycodone product, you may notice tablet shells in your stool. There is no cause for alarm; the outer coating is not absorbed and passes through your gut. Your body still absorbs the medication from the tablet.
- If you forget to take your usual oxycodone dose on time, you can take it very soon thereafter. Otherwise, wait until it is time for the next dose and take only that; *do not* take extra oxycodone to make up for what was missed.
- To help avoid missing doses or taking extra ones, use a dosing chart or medication log to keep track of when you take each dose of oxycodone. This is especially helpful if you were prescribed a short-acting product to take for "breakthrough" pain or "as needed."
- If you are forgetful, have someone else give you each dose of oxycodone and keep a record of it.
- Tell *all* of your healthcare providers that you are taking oxycodone. Unless they know of this, they might prescribe medications that may alter the effects of oxycodone. If there are questions, you should contact the oxycodone prescriber.

Taking extra oxycodone, more often, or with other drugs or alcohol can be harmful or even fatal.

A grid for tracking medication. The title is "Weekly Medication Chart". The columns are labeled: "Medication Name", "Dose", "Time", "Day", "Mon", "Tue", "Wed", "Thu", "Fri", "Sat", "Sun". There are 7 rows for tracking. Below the grid, there is a small note: "Source: Adapted from the American Society of Health-System Pharmacists."/>

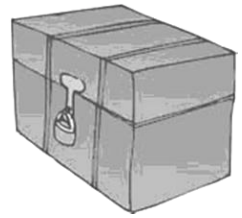
Medication Name	Dose	Time	Day	Mon	Tue	Wed	Thu	Fri	Sat	Sun

Keep careful track of when you take your oxycodone.

Store oxycodone safely.

Oxycodone absolutely must be kept in a safe place where others – children or adults –cannot gain access to it. A single tablet of oxycodone can be harmful, or even fatal, in an individual who is not used to the medication.

- Do not keep oxycodone on kitchen counters, in bathroom cabinets, or other obvious places. If necessary, store oxycodone in a locked box or cabinet and in an out of the way location.
- Remember, persons you may least suspect, such as family members or visitors, might look for drugs like oxycodone to use for illegal purposes.
- Never share your oxycodone with anyone else, since it could do them great harm.



What are oxycodone side effects to watch for?

Alert your family members or caregivers of important warning signs to watch for that may indicate you are reacting badly to oxycodone and are in distress. If you experience any of the following, they should call for emergency help:

- **Trouble staying awake.** ■ **Difficult or slow breathing.**
- **Loud or unusual snoring at night and difficulty being awakened.**
- **Fast heartbeat, unusual dizziness, or loss of consciousness (fainting).**
- Oxycodone, like all other opioids, may cause constipation. Your healthcare provider or pharmacist can recommend approaches for preventing or treating this. Reducing the oxycodone dose on your own *will not help*.
- Certain side effects, if they occur at all, usually become milder or go away with time, such as a lightheaded feeling, nausea, stomach upset, or mild drowsiness. Be careful with other medications that may cause drowsiness, like allergy, cough or cold medicines, sleeping medicine, medicine for anxiety, or other pain medicine. **DO NOT** drink alcohol while taking oxycodone.
- Possible other side effects may be more long-lasting, including: itching, dry mouth, flushing, or increased sweating. Allergic reactions to oxycodone – including rash, hives, or swelling – are rare but require prompt medical attention.
- Uncommon side effects include confusion, mood changes (depression or agitation), shaking, blurred vision, or difficulty urinating. If you experience any of these, tell your healthcare provider.
- You should refrain from driving and other activities requiring balance or focused concentration until the effects of oxycodone are known, typically a week or longer.



Will you become dependent on or addicted to oxycodone?

- After awhile, oxycodone causes *physical dependence*. That is, if you suddenly stop the medication you may experience uncomfortable withdrawal symptoms, such as diarrhea, body aches, weakness, restlessness, anxiety, loss of appetite, and other ill feelings. These may take several days to develop.
- This is not the same as *addiction*, a disease involving craving for the drug, loss of control over taking it or compulsive use, and using it despite harm. Addiction to oxycodone in persons without a recent history of alcohol or drug problems is rare.
- If you ever want to stop taking oxycodone, do not do so on your own. Gradually reducing the dose as directed by your healthcare provider will help prevent uncomfortable withdrawal reactions.

Do not reduce or stop taking oxycodone on your own.

Instrucciones para el paciente



Cómo tomar oxycodone sin ningún peligro

Sírvase leer este folleto atentamente y compartirlo con su familia o cuidadores.

Esto no sustituye la orientación del proveedor del cuidado de la salud ni el inserto que viene dentro de la caja de oxycodone.

Su proveedor del cuidado de la salud le ha recetado oxycodone para el alivio del dolor. Es un calmante fuerte para el dolor que se ha usado con mucho éxito por muchos años en millones de personas en todo el mundo. Es un fármaco opioide semi-artificial, sintético, con efectos similares a los opioides naturales tales como la morfina o codeína que provienen de la amapola del opio. El oxycodone es muy efectivo; sin embargo el uso inadecuado o el abuso pueden ser dañinos e incluso fatales (puede causar la muerte). **Por consiguiente, es muy importante que usted lea, entienda y siga las instrucciones de seguridad mencionadas a continuación.**

Siempre tome el oxycodone exactamente como se lo han indicado.

Tomar oxycodone en exceso o combinarlo con otros fármacos, alcohol o productos no recetados, a menos que su proveedor del cuidado de la salud lo apruebe, puede ser dañino o incluso mortal.

Tomar oxycodone, en exceso, muy a menudo, o con otros fármacos o alcohol puede ser dañino o incluso mortal.

- Asegúrese de informarle a su profesional de la salud acerca de todos los productos para el cuidado de la salud y medicamentos (recetados y no recetados) que está usando y su historial completo de salud. Algunas veces el oxycodone se combina con otros medicamentos tales como el paracetamol (acetaminofén) o el ibuprofeno que se pueden adquirir por venta libre también. El ingerir grandes cantidades de estos productos puede ser perjudicial.
- Usted debe tomar la cantidad recetada de oxycodone y a las horas indicadas.
- Si le recetaran el producto oxycodone de efecto prolongado, no triture, parta o altere la tableta de ningún modo. Esto cambiará los efectos del oxycodone y puede causar una sobredosis y posiblemente la muerte.
- Si le recetaran la solución oral del oxycodone, consulte con su farmacéutico acerca de usar la cucharilla de medición apropiada o gotero de medición de dosis. El uso de una cuchara doméstica no es nada precisa y se puede ingerir una cantidad que sea perjudicial.
- Usted puede tomar el medicamento oxycodone con o sin alimentos.
- Si le recetaran el producto de oxycodone de efecto prolongado, usted puede observar las cáscaras del comprimido en las heces. No hay motivo para alarmarse. La capa exterior no se absorbe y recorre los intestinos. Su organismo sigue absorbiendo el medicamento de la tableta.
- Si se olvida de tomar la dosis habitual de oxycodone a tiempo, usted puede tomarla inmediatamente después. De lo contrario, espere hasta que sea la hora de la próxima dosis y solamente tome esa dosis; no tome oxycodone adicional para compensar la que olvidó tomar.
- Para evitar que se olvide de la dosis o que tome una dosis de más, utilice un registro o diario de medicamentos para ayudarle a llevar cuenta de cuándo toma cada dosis de oxycodone. Esto es especialmente útil si le recetaran un producto de poca duración para el dolor "impetuoso y repentino" o "cuando lo necesite."
- Si usted es olvidadizo(a), pídale a alguien que le dé las dosis de oxycodone y lleve un registro de cada una de ellas.
- Infórmeles a todos sus proveedores del cuidado de la salud de que usted está tomando oxycodone. A no ser que se les avise, ellos le pueden recetar medicamentos que puedan alterar los efectos del oxycodone. De tener alguna pregunta, usted debe ponerse en contacto con la persona que le recetó el oxycodone.

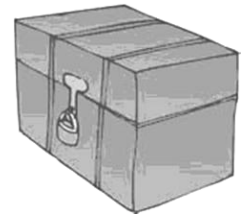
Medication Name	Color/Shape	Dose	Time	Day	Mon	Tue	Wed	Thu	Fri	Sat	Sun

Lleve un registro minucioso de sus tomas de oxycodone.

Guarde el oxycodone en un lugar seguro.

El oxycodone se debe guardar en un lugar absolutamente seguro donde otras personas, tanto niños como adultos, no puedan tener acceso. Una sola tableta de oxycodone puede ser dañina, inclusive mortal, en una persona que no está acostumbrada al medicamento.

- No guarde el oxycodone en los armarios de la cocina, del cuarto de baño u otros sitios fácilmente accesibles. De ser necesario, guarde el oxycodone en una caja o armario con llave y en un lugar fuera del alcance.
- Recuerde que las personas de las que menos sospecha, tales como familiares o visitas, podrían estar en busca de fármacos como el oxycodone para usarlo con fines ilegales.
- Nunca comparta el oxycodone con nadie más debido a que les podría causar un gran daño.



¿Cuáles son los efectos secundarios del oxycodone a los que se deben estar alertas?

Alerte a sus familiares o cuidadores sobre las señales importantes de peligro a las que deben estar alertas ya que pueden indicar que usted está teniendo una mala reacción al oxycodone y se encuentra en peligro. Si usted experimenta cualquiera de los siguientes síntomas, estas personas deberían pedir ayuda de emergencia:

- Problemas para mantenerse despierto. ■ Dificultad para respirar o respiración lenta.
 - Un ronquido fuerte o extraño en la noche y dificultad para despertarse.
 - Palpitaciones, mareos no usuales o pérdida del conocimiento (desmayo).
- El oxycodone, como todos los demás opioides, puede causar estreñimiento. Su proveedor del cuidado de la salud o farmacéutico le puede recomendar medidas para prevenirlo o darle tratamiento. Reducir la dosis de oxycodone por su cuenta no le ayudará.
 - Algunos efectos secundarios, de ocurrir, generalmente se vuelven más leves o desaparecen con el tiempo, tales como la sensación de mareo, náuseas, malestar estomacal o somnolencia leve. Tenga precaución con otros medicamentos que puedan causarle somnolencia, tales como los antihistamínicos, medicina para la tos o resfriados, medicamento para dormir, medicina para la ansiedad u otros calmantes para el dolor. NO consuma alcohol mientras tome el oxycodone.
 - Otros posibles efectos secundarios pueden ser de larga duración, incluyendo: comezón, sequedad bucal, enrojecimiento o aumento en la sudoración. Las reacciones alérgicas al oxycodone – incluyendo erupción, urticaria o hinchazón – son poco comunes pero requieren de una atención médica rápida.
 - Los efectos secundarios poco corrientes incluyen confusión, cambios de humor (depresión o ansiedad), tembladera, visión borrosa o dificultad al orinar. Si usted experimenta cualquiera de estos síntomas, infórmele a su proveedor del cuidado de la salud.
 - Debe evitar manejar y hacer otras actividades que requieran de equilibrio o mucha concentración hasta que usted sepa cuáles son los efectos del oxycodone, por lo general en una semana o más.



¿Se volverá dependiente o adicto al oxycodone?

- Después de un tiempo, el oxycodone causa dependencia física. Esto quiere decir que si usted deja de tomar el medicamento repentinamente, usted puede experimentar síntomas molestos de abstinencia, tales como diarrea, dolores corporales, debilidad, inquietud, ansiedad, pérdida del apetito y otras sensaciones de malestar. Esto puede tomar varios días en aparecer.
- Esto no es lo mismo que la adicción, una enfermedad que implica un ansia por el fármaco, pérdida del control al tomarlo o el uso compulsivo, y usarlo a pesar del daño que ocasione. La adicción al oxycodone en las personas sin un historial reciente de problemas de alcohol o drogas es poco común.
- Si alguna vez usted desea dejar de tomar el oxycodone, no lo haga por cuenta propia. La reducción gradual de la dosis tal como se lo indique su proveedor del cuidado de la salud le ayudará a prevenir reacciones molestas de abstinencia.

No reduzca ni suspenda el oxycodone por su cuenta.