

Opioid Medications and REMS: A Patient's Guide

READY FOR
REMS 

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Things You Should Know About Your Opioid Medication

Opioid medications are an important part of pain treatment.

- > Most people with long-term pain require a combination of treatments to properly relieve their pain. These treatments, which should only be given under the direction of a knowledgeable healthcare professional, may include medicines, physical and psychological therapy, devices, or surgery. Some patients find that non-traditional treatments, such as meditation, acupuncture, massage, and complementary medicines, can help too, but you should always check with your doctor before trying any of these. Psychological treatment approaches, such as cognitive behavioral therapy, involving modifying negative thoughts related to long-term pain, have also been found to be effective in helping to reduce pain, disability, and anxiety.
- > Prescription medication is the most common treatment for long-term pain, and opioid medications are a useful option doctors may use to treat some people with severe, long-term pain. Your doctor may suggest that an opioid might be the best medicine for you, but patients on opioids need to be monitored to determine if opioids should be continued.



Opioid medications are associated with certain risks.

- > When used as directed, opioid medications can be highly effective for controlling pain and improving functioning in many people.
- > Opioid medications are strong painkillers and have certain risks, particularly if they are taken in a way that is not intended by your doctor. These risks include overdose, abuse, and addiction. Overdose, which may be due to abuse or addiction, can be fatal.

- > Some people are nervous about taking opioids because they are afraid they will become addicted. However, patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids. If you find yourself taking your opioids more often than you should, or you feel a craving for them, then it is important to talk to your doctor. It is not a sign of addiction if you find that you need increasing amounts of an opioid to control your pain (which may be tolerance to pain relief), or if you experience unpleasant symptoms when your opioid is suddenly stopped (withdrawal due to physical dependence), or if, over time, some of the opioid side effects, like nausea, become less bothersome to you (tolerance to side effects).
- > Certain opioid medications are so powerful that they can only be used in patients who have already built up a tolerance to opioids; such opioids may prove harmful or even lethal in people who have not first developed a tolerance.

Risk Evaluation and Mitigation Strategies, or REMS.

- > Risk Evaluation and Mitigation Strategies, also called REMS, are programs required by the US Food and Drug Administration to promote the safe use and distribution of certain prescription medications, including opioids. They are intended to make sure that the benefits outweigh the risks, such as overdose.
- > REMS may continually educate both healthcare providers and patients about safety with regard to opioids, and may create certain procedures for obtaining and dispensing such drugs.
- > Your doctor will talk with you about safety and necessary precautions, confirming that you have understood what has been discussed. You will also be given a medication guide. This is a pamphlet outlining the nature and purpose of the opioid medication as well as the benefits and risks (see *Read your medication guide*).
- > Once in place, REMS programs must be followed. Currently, some opioid medications have a REMS while others do not yet have one. In the meantime, we will give you some general information that you can use now to help keep you safe while taking your opioid medication. Your healthcare provider will talk to you about other responsibilities for specific opioid REMS as they are introduced.

Things You Should Know About Treating Your Pain

Pain management involves a team.

- > Pain management often involves a team that includes the patient, the doctor or other prescriber, a nurse, and a pharmacist, and sometimes a caregiver, family member, or counselor. Because pain is complex, your response to a treatment must be closely monitored to ensure it is right for you. Your doctor may also ask that you consult with a pain specialist, a physical or occupational therapist, an addiction specialist, or a behavioral therapist to help you manage your pain.



Your medical history.

- > Your doctor may ask you a lot of questions about your medical history. To make sure you receive the best treatment you should be open and honest about:
 - what medications you are taking (including over-the-counter preparations, nutritional supplements, vitamins, herbal remedies, etc).
 - how much alcohol or tobacco products you consume.



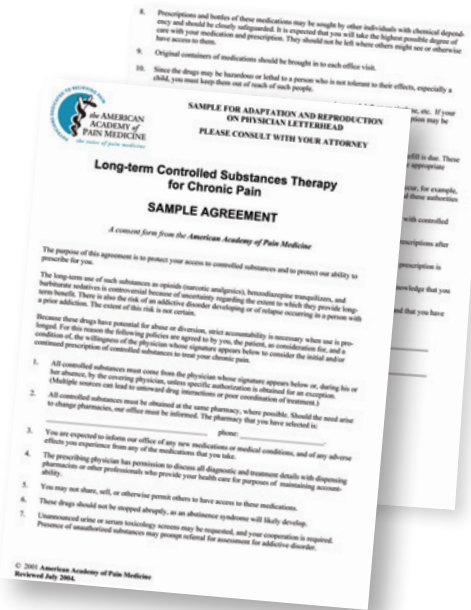
- other aspects of your personal and family history, including any history of substance abuse (ie, non-medical use of drugs or excessive use of alcohol or tobacco). Remember, talking honestly about your medical history and any history of addiction you may have should not disqualify you from pain treatment, but can help your doctor make a safe treatment plan for you.

Make sure you understand.

- > Before starting treatment, your doctor may ask you to read information about your opioid medication and its risks, as well as the best way to manage side effects. You should use this opportunity to ask questions about your treatment so that you understand all the aspects involved (eg, goals of treatment, potential benefits, side effects, interactions with other medications, other choices, etc).

You may be asked by your doctor to sign paperwork

stating that you understand what he or she has explained to you. This is known as *informed consent* or an *opioid agreement*.



Things You Should Know Before You Take Opioid Medications

Monitoring for effectiveness and safety.

- > While you are taking an opioid medication your doctor will monitor you closely to ensure that you use the medication as prescribed and that the benefits of opioid therapy (including improved quality of life) outweigh the risks. Monitoring may involve regular testing of urine samples and keeping a pain diary, both of which will be explained by your doctor.

Precautions you should take for safe use of your opioid medications.

- > There are important things that you can do to ensure that you are using your opioid medications appropriately and safely:

Adhere to your dosing schedule

- Always take your opioid medications exactly as prescribed by your doctor. Never change the dose without talking to your doctor, nurse, or pharmacist first, as this could be very dangerous.

Read your medication guide

- The medication guide is a concise educational document that should be given to you every time that an opioid is prescribed by your doctor or dispensed by the pharmacist. The medication guide contains information about the medication, including the active ingredient, the dosage, how it works in the body, and its side effects. If you do not receive one with every prescription, then you should ask your doctor or pharmacist for one, because the information may have been updated since your last prescription.

Safely store your opioid medication

- Keep your opioid medication stored in a safe, secure, dry place, where a pet, child, teenager, or stranger cannot get to it. If anyone else takes your opioid medication he or she can die. Do not store opioids in many different locations around the home. In particular, ensure that the medicine is kept away from young children who may accidentally ingest your medication. Always keep the tablets in a bottle with a child-resistant lid, and keep the bottle in a secure lockbox that is approved by your doctor.
- Guard your opioid medication against theft. Some people may steal medications to use themselves (a case of drug abuse) or to sell to their friends or to strangers (a case of diversion). Stealing a controlled substance like an opioid medication is very serious, and you can help to prevent this by safely storing your medicines in a lockbox. Make sure that only you and your caregiver have access to the lockbox.



Never share your opioid medication

- Your opioid medication is for one person only: you. It is illegal to share your medication with anyone, even with friends or family members who may have the same condition and tell you that they need it because they are feeling pain. A medication that works for you can be very dangerous for someone else, and even a single pill can prove fatal to another person.



Dispose of leftover medication

- Expired and unused opioid medication should never be saved. If you have changed your opioid medication, then you must dispose of your leftover medication safely. Disposal should be conducted as described in the accompanying medication guide, or as directed by your doctor or pharmacist. Some opioid medications can be flushed down the toilet; other kinds should be broken up and mixed with coffee grounds, cat litter, etc, before disposal. (This will make the medication less tempting to children or pets and unrecognizable to people who may intentionally search through your trash.)
- Please note, however, that some communities have restrictions regarding flushing medicines down the toilet. When in doubt check with your local water treatment and/or sanitation department regarding how to safely dispose of medicines in your community. Labeling should also be removed to protect your identity.

Don't Be Afraid To Ask

- > Opioids are an important option for treating pain, and, when used safely by following these tips, the risks of misuse, abuse, and overdose can be managed. Risk Evaluation Mitigation Strategies (REMS) are programs designed to help everyone remember and follow safe use tips. Always feel free to discuss any questions or concerns that you may have with your healthcare provider.

Recommended Reading For Patients

Brown MA. FAQ: When opioids have been prescribed for my chronic pain. <http://www.painfoundation.org/learn/library/pain-topics/medication/faq-opioids.html>. Updated August 4, 2009.

Kaiser Permanente Medical Group, Inc. Opioid therapy for chronic pain: What to expect. <http://www.permanente.net/homepage/kaiser/pdf/52613.pdf>. Revised September 2009.

WebMD. Pain management: Drug tolerance and addiction. <http://www.webmd.com/pain-management/guide/drug-tolerance-addiction>. Edited November 1, 2007.