What you should know about treating your pain with opioids

Important information on the safe use of opioid pain medicine.
If your healthcare provider has determined that opioid therapy is right for you, it is important to read this entire brochure.

**Introduction to opioids and the possible risks from taking them**

Opioids (OH-pee-oyds) are a type of pain medicine (narcotic) that are used to treat severe pain requiring around-the-clock, long-term treatment. When pain is not adequately managed by other treatments, opioids can be useful therapy; however, opioids can harm you if you use them the wrong way. The risk of harm goes hand-in-hand with the benefit of pain relief. This brochure will help educate you on these risks.

**Possible risks from taking opioids include:**

- Adverse events
- Misuse
- Abuse
- Physical dependence
- Addiction
- Overdose
- Death
- Interaction with alcohol, benzodiazepines, and other CNS depressants

**Table of contents**

- Opioids and risks 3
- Side effects of opioid therapy 4
- Misuse, abuse, physical dependence, and addiction 4
- Who is at risk for addiction? 6
- Taking opioids as prescribed 7
- Pain relief and tolerance 8
- An opioid treatment plan 10
- Starting treatment 11
- What to expect from your healthcare provider 12
- Patient responsibility 12
- Keeping your medicine safe 14
- Important Safety Information 16
What are some of the possible side effects of opioid therapy?

Opioids can help reduce both sudden (acute) and ongoing (chronic) pain. But there are some possible side effects with opioid therapy:

- Breathing problems
- Constipation
- Confusion
- Itching
- Drowsiness
- Nausea

Serious side effects, such as breathing problems or death, have been associated with opioid therapy. Get emergency medical help if you have trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, throat, or hands, itching, rash, extreme drowsiness, are feeling faint, have agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

Your healthcare provider can help to explain and, in some cases, minimize side effects that may occur as a result of opioid treatment. These are not all the possible side effects of opioid therapy. If you notice any side effects, you should let your healthcare provider know right away.

What are the differences between misuse, abuse, physical dependence, and addiction?

**Misuse** is when a prescription drug is used for relief or treatment, but in a way other than directed by a healthcare provider. Misuse involves taking more or less drug than needed, taking it at different times than prescribed, or taking it for a different condition. Taking a drug that has been prescribed for someone else is also misuse.

**Abuse** is when a drug is intentionally used to get high or relieve anxiety, and not to treat the medical condition it was prescribed for. This pattern of drug use could result in bad outcomes, such as illness, physical discomfort, or even death, failure to perform at work, school, or home, legal issues, or problems with loved ones.

**Physical dependence** refers to changes in the way your body responds to a drug. Long-term use can also result in your body being dependent on that drug. In this case, if you quickly reduce the dose or stop taking the drug, your body will have uncomfortable symptoms called “withdrawal.”

Common symptoms of withdrawal include nausea, diarrhea, coughing, sweating, or increased blood pressure or breathing. Symptoms of withdrawal can be avoided by slowly decreasing your opioid dose under the supervision of your healthcare provider. You should not change your dose on your own or stop taking the drug without talking to your healthcare provider. Speak with your healthcare provider if you feel that you need to have your medicine adjusted.

In some cases, withdrawal symptoms could be very dangerous. Life-threatening symptoms could include breathing problems, such as shortness of breath, shallow breathing, dizziness, or confusion. If any of these symptoms occur, call your healthcare provider or get medical help right away.

**Addiction** involves a group of behavioral, mental, and emotional issues that can occur after using substances.
Who may be at greater risk for addiction?

Addiction and abuse are more likely to happen if you smoke, already have a drug or alcohol problem, or if you have used illegal drugs in the past. If you have abused alcohol or drugs in the past, you may need to work with an addiction specialist while being treated with opioid medicine. Your healthcare provider can recommend an addiction specialist to help you manage the use of opioids to relieve your pain.

Patients who become addicted to opioids will show the following behaviors, known as the 4 C’s:

- Loss of control over drug use
- Compulsive drug use
- Continued drug use even when it damages the body, the mind, or relationships
- Craving

Even if you take your dose correctly as prescribed, you are at risk for opioid addiction, abuse, and misuse that can lead to death.

There is help for people recovering from active addiction. It is important to reach out to your healthcare provider for assistance and recognize that sometimes several rounds of addiction treatments are necessary. Therefore, it is important not to give up.

Take your opioids as prescribed

Your healthcare provider will tell you how to take your medicine and how many doses you need to take.

Remember to:

- Never adjust the amount or frequency of your medicine without discussing with your healthcare provider
- Do not stop taking your medication without talking to your healthcare provider
- Never mix your medicine with other opioid medications, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs). Taking opioids with alcohol or certain other medications may increase your risk of dangerous side effects and can lead to death
- Always tell your healthcare provider about all medicines you are taking or plan to take, including over-the-counter medicines and supplements
- Keep track of when you take all of your medicines
- Always ask for help when it is needed

It is extremely important to take opioids only as instructed by your healthcare provider and never share your medicine, even with someone who is suffering from the same pain as you, as they can die from taking it.

It is important to know what to expect while taking an opioid medicine. Opioids provide effective relief for many short-term and chronic conditions, but should not always be expected to completely relieve all your pain. Taking more tablets than prescribed in order to relieve all of your pain is dangerous because of the life-threatening side effects and the risk of physical dependence.
You may find over time that your medicine is not working as well to relieve your pain as when you first started taking it. This may be because your body has built up a tolerance to the medicine. 

**Tolerance** means that your body gets used to the medicine so that the opioid does not control your pain as well as it used to. The pain may come back sooner.

If you need more pain relief, are having trouble sleeping, or are feeling depressed, tell your healthcare provider. Treatments may be available, but a healthcare provider must always be the one to add medicine, change a prescription, or adjust the dose. Medication may be one part of the solution. Other important options include exercise and physical therapy, stress reduction techniques, such as biofeedback and hypnosis, and interventional alternatives, which include injections or surgery.
To be successful on your opioid treatment, you need a plan

Your healthcare provider will do a physical examination and may ask you questions about your illness or injury and your pain. He or she may ask about your and your family’s health history, and may even collect blood samples and perform other tests. With this information, your healthcare provider can talk to you about your treatment options.

Your healthcare provider will work with you to develop a treatment plan or agreement. This plan may include:

- Treatment goals
- The right way to take opioid medicines
- Information about other treatment options and specialists
- How to avoid misuse and abuse

It can be helpful to develop a goal for treatment and to discuss this goal, as well as the expectations of your treatment, at each visit with your healthcare provider in order to determine if your current therapy is appropriate. Use the space below to take notes.

Starting treatment

Many people start opioid treatment on a trial basis. During this time, healthcare providers can see how well the medicine is working and if you have any side effects. Most people start with a low dose of opioid medicine. Your healthcare provider may adjust that dose until your pain is controlled.

Opioids do not work for everyone. An opioid may not take away all of your pain. Treatment goals should be discussed with your healthcare provider before you begin the medication.

Monitoring

You will need to see your healthcare provider for regular checkups. During these visits, your healthcare provider will ask you how the medicine is working to relieve your pain and if you are experiencing any side effects. Your healthcare provider will also talk with you to learn if changes to your treatment plan are needed.

Your healthcare provider may also ask you about your use of the medicine to make sure you are taking it correctly. You may also have to provide a blood or urine sample to confirm that you are taking the medicine as prescribed. These requests are common in opioid treatment.
What to expect from your healthcare provider

Pain is a very personal experience that can be difficult to explain to other people. Many patients with pain worry that they are not being taken seriously. Your healthcare provider is used to dealing with people in pain, and he or she is trained to:

• Listen to you when you describe and explain your pain
• Understand the pain you have described
• Explain why you have pain

You and your healthcare provider will work together to determine what treatment option is right for you and to ensure your pain is treated as effectively and safely as possible.

Patient responsibilities while taking opioids

Healthcare providers have expectations of patients as well, especially those taking opioids. When meeting with your healthcare provider, be prepared to:

• Provide accurate and detailed information, including past medical records
• Always tell your healthcare provider about all medicines you are taking or plan to take, including over-the-counter medicines and supplements
• Discuss treatment goals and expectations
• Follow your healthcare provider’s directions
• Keep all medicines safe and secure
• Agree upon a treatment plan with your healthcare provider
• Use the same healthcare provider and pharmacy for any of your opioid medicines
Thousands of people die every year because of opioid misuse and abuse. Drug theft is a common way people obtain prescription drugs for illegal use. People steal drugs for their own misuse and/or to sell illegally. For people who are not prescribed opioids by a healthcare provider, taking an opioid can be harmful and, in some cases, deadly. Opioids are strong pain medicines that can cause life-threatening problems.

You are responsible for your medicine and for keeping it in a safe place where it cannot be stolen.

Steps for the safe and proper storage of opioid medicine:

• Do not share your medicine with anyone
• Limit access to your opioid medicine to you and your caregivers only
• Lock your medicine in a cabinet or box and secure the key
• Keep all medicines out of reach of any children
• Do not use a bathroom cabinet because they rarely lock and are the first place any stranger or visitor in your house will look

• Make sure that you have the correct number of tablets when you get your prescription and count the number you have left on a regular basis. If tablets are missing, discuss it with your immediate family or anyone else you share your house with

• Evaluate the risk you have in your home, including such possible situations as:
  o Presence of young children
  o Presence of teens or young adults
  o Visitors or family who may have a history of drug abuse, addiction, or mental health problems

• Dispose of your unused opioid pain medicine as soon as it is no longer needed
  o Ask your pharmacist or read the disposal instructions located in the package insert that came with your medicine
OPANA® ER IS:
• A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage pain severe enough to require daily, around-the-clock, long-term treatment with an opioid when other pain treatments, such as non-opioid pain medicines or immediate-release opioid medicines, do not treat your pain well enough or you cannot tolerate them.
• A long-acting (extended-release) 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.
• Not for use to treat pain that is not around-the-clock.

IMPORTANT SAFETY INFORMATION ABOUT OPANA® ER
• Get emergency help right away if you take too much OPANA® ER (overdose). When you first start taking OPANA® ER, 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.
• Taking OPANA® ER with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, low blood pressure upon standing, fainting, coma, and death.
• Never give anyone your OPANA® ER. They could die from taking it. Store OPANA® ER away from children and in a safe place to prevent stealing or abuse. Selling or giving away OPANA® ER is against the law.

Do not take OPANA® ER if you have:
• Severe asthma, trouble breathing, or other lung problems
• A bowel blockage or have narrowing of the stomach or intestines

Before taking OPANA® ER, tell your healthcare provider if you have a history of:
• Head injury
• Seizures or convulsive disorders as you may experience seizures while taking OPANA® ER
• Problems urinating
• Liver, kidney, thyroid problems
• Pancreas or gallbladder problems
• Abuse of street or prescription drugs, alcohol addiction, or mental health problems

Tell your healthcare provider if you are:
• Pregnant or planning to become pregnant. Prolonged use of OPANA® ER during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
• Breastfeeding. Not recommended during treatment with OPANA® ER. It may harm your baby.
• Taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking OPANA® ER with certain other medicines can cause serious side effects that could lead to death.

When taking OPANA® ER:
• Do not change your dose. Take OPANA® ER exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed
• Take your prescribed dose every 12 hours at the same time every day on an empty stomach, at least 1 hour before or 2 hours after meals. Do not take more than your prescribed dose in 24 hours. If you miss a dose, take your next dose at your usual time.
• Swallow OPANA® ER whole. Do not cut, break, chew, crush, dissolve, snort, or inject OPANA® ER, because this may cause you to overdose and die.
• To avoid choking on the tablet, OPANA® ER should be taken 1 tablet at a time. Do not pre-soak, lick, or wet the tablet before placing in your mouth.
• Call your healthcare provider if the dose you are taking does not control your pain.
• Do not stop taking OPANA® ER without talking to your healthcare provider.
• After you stop taking OPANA® ER, flush any unused tablets down the toilet.

While taking OPANA® ER, DO NOT:
• Drive or operate heavy machinery, until you know how OPANA® ER affects you. OPANA® ER 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 OPANA® ER may cause you to overdose and die.

Possible side effects of OPANA® ER include:
• Constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain.

Call your healthcare provider if any of these symptoms are severe.

Get emergency medical help if you have:
• Trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, throat or hands, hives, itching, rash, 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 OPANA® ER. Call your doctor for medical advice about side effects. You may report side effects to FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

Please click here for full Prescribing Information, including Boxed WARNING and Medication Guide.
Using opioids safely is important to get proper pain relief and to avoid potentially serious side effects

- When starting a new opioid medicine, discuss goals and expectations with your healthcare provider
- Take your medicine only as instructed; never take it more often
- Meet with your healthcare provider regularly to discuss how well the medicine is relieving your pain
- Keep your medicine safe and never share it with anyone else