



IT'S YOUR HEALTH



Opioid Pain Medications Frequently Asked Questions

What is an opioid?

Opioids are a broad range of natural and manufactured (synthetic) compounds that are commonly used for pain relief.

There are three main groups of opioid drugs:

- **Naturally occurring:** These are made from the liquid harvested from the unripe seed pods of the opium poppy flower. Examples include codeine and morphine.
- **Semi-synthetic:** These are made by modifying the chemical structure of a naturally occurring opioid. Examples include heroin and oxycodone.
- **Synthetic:** These compounds are manufactured chemicals. Examples include meperidine and methadone.

All opioids produce similar effects. The main differences between opioids are their potency (how much drug is needed to produce an effect) and duration of their action (how long the effect(s) last). For example, short-acting opioids need to be taken every three to six hours to maintain the effect, while long-acting opioids need to be taken less often; i.e., only once or twice a day. Some pharmaceutical preparations are designed to release opioids slowly, and

therefore, the medication needs to be taken less often.

How do opioids work?

Regardless of how an opioid drug enters the body (for example, by mouth, by a needle, or by a patch on the skin) it works by interacting with proteins in the body called “opioid receptors”. A number of different types of opioid receptors exist in the body that are responsible for different opioid effects (desirable or undesirable). These receptors are found in the brain, the spinal cord and the gastrointestinal tract. Opioid drugs reach these receptors by travelling through the bloodstream.

What are opioids used for?

Opioids are primarily used to manage different types of pain. They are also used to control moderate to severe cough, to control diarrhea and to treat addiction to other opioids such as heroin.

What are some examples of prescription opioid medications?

Opioid Active Ingredient 1	Product Names
BUTORPHANOL	APO-BUTORPHANOL PMS-BUTORPHANOL
CODEINE	ATASOL 282 TABLETS 292 TABLETS CODEINE CONTIN CONTROLLED RELEASE COACTIFED EXDOL TYLENOL WITH CODEINE NO. 1 TYLENOL WITH CODEINE NO. 2 TYLENOL WITH CODEINE NO. 3 TYLENOL WITH CODEINE NO. 4
FENTANYL	DURAGESIC
HYDROCODONE	DALMACOL HYCODAN TUSSIONEX
HYDROMORPHONE	DILAUDID HYDROMORPH CONTIN CONTROLLED RELEASE HYDROMORPH.IR
MEPERIDINE	DEMEROL
MORPHINE	DOLORAL 1 (Syrup and Tablets) MS CONTIN M-ESLON KADIAN STATEX
OXYCODONE	OXY.IR OXYCONTIN PERCOCET PERCODAN ENDOCET SUPEUDOL
PENTAZOCINE	TALWIN
PROPOXYPHENE	DARVON

Other ingredients may be present in these preparations. Only opioid ingredients are listed in the table.

What are the risks associated with opioid medications?

Like all medications, opioids have benefits and risks. Common side effects associated with opioids include nausea and vomiting, drowsiness, itching, dry mouth and constipation. Less common side effects include dizziness, confusion, hallucinations, delirium, urinary retention and dose-related respiratory depression. Abuse of opioid medications can have serious health consequences and may lead to addiction. When used as directed, opioid medications are considered effective and their side effects are generally manageable. Drowsiness and nausea, for example, are usually experienced at the beginning of opioid treatment and tend to improve within a few days. Medication to counter constipation may be recommended with long-term opioid treatment.

Health care professionals, who are familiar with the medical history of an individual, along with the patient themselves, are best placed to determine the most appropriate treatment for an individual. Good patient/doctor communication is an essential risk management tool for all drugs, including opioids.

Why are some opioid products allowed to be sold over-the-counter (OTC) while others require a prescription? Are they less dangerous than prescription opioid products?



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To be permitted for sale over-the-counter (OTC), an opioid preparation must contain a very low dose of an opioid in combination with two or more other medicinal ingredients. Examples of OTC opioid-containing products are cough medicines and pain medicines that contain a low dose of codeine along with acetaminophen, acetylsalicylic acid (ASA) or caffeine. Products used for the same purpose containing a higher dose of opioid may also be marketed in Canada, but by prescription only because of their higher opioid content. These products are more likely to induce a stronger opioid effect.

The fact that a medication is bought over-the-counter does not make it safer than a prescription medication. Like any medication, OTC medications pose risks if they are not used according to instructions; i.e., taking the recommended dose at the recommended time interval. Inappropriate use (e.g. taking more than the recommended amount or taking multiple OTC products simultaneously) can lead to overdose (i.e., an excessive dose of a drug which is toxic and may lead to death). When using OTC products containing an opioid in combination with other medicinal products, such as acetylsalicylic acid (ASA) or acetaminophen, the risk of overdose relates to both opioid and non-opioid medicinal ingredients.

How can I find out more information about the specific opioid medication that I am taking?

For more information on the specific opioid(s) you are taking, you should talk to your doctor or pharmacist. You can also get up-to-date information by looking at the official Canadian product monograph. Product monographs are factual, scientific documents that contain information regarding the optimal and safe use of a drug. Health Canada-authorized, product monographs for some opioid medications are available by searching Health Canada's Drug Product Database (DPD) at www.hc-sc.gc.ca/dhp-mps/prodpharma/databasdon/index-eng.php.

For more information on product monographs and searching the Drug Product Database, visit these Frequently Asked Questions at www.hc-sc.gc.ca/dhp-mps/prodpharma/activit/proj/monograph-rev/pm_qa_mp_qr-eng.php.

What do I do if I or someone I know has a side effect from taking an opioid?

You should contact your physician and discuss this with them. For any health effect requiring immediate attention, such as slow breathing, or confusion, or extreme sleepiness, call 9-1-1 or your

local emergency department as soon as possible.

Side effects can also be reported to Health Canada's Canada Vigilance Program in the following three ways:

Report online at the MedEffect™ Canada Web section (www.medeffect.com)

Call toll-free at 1-866-234-2345

Complete a Canada Vigilance Reporting Form at www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/ar-ei_form-eng.php and either fax toll-free to 1-866-678-6789

or mail to:

Canada Vigilance Program
Health Canada
AL 0701C
Ottawa, ON K1A 0K9

To have postage pre-paid, download the postage paid label from the MedEffect™ Canada Web section at www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/post_paid-affranchi-eng.php

The Canada Vigilance Reporting Form and the adverse reaction reporting guidelines may also be obtained via this Web site.

Are opioids addictive?

All opioids can be addictive, no matter how they are obtained or what they are used for. Addiction refers to the compulsive use of a drug despite negative consequences. Individuals with a personal or family history of substance abuse, including alcohol, may be at higher risk of addiction to opioid pain medications.

The regular use of opioids, including for medical purposes, can lead to physical dependence, a natural reaction which occurs when the body

gets used to having a certain drug in the system. Physical dependence should not be confused with addiction. While a person may be physically dependent on a drug, they are not necessarily addicted. If a person who is physically dependent on an opioid suddenly stops taking it, he/she will experience symptoms of withdrawal (refer to the *It's Your Health* article on Opioid Pain Medications at www.hc-sc.gc.ca/hl-vs/iyh-vsv/med/ana-opioid-med-eng.php for more information). These symptoms can be minimized and it is important that patients consult their health care professional prior to ending the use of an opioid medication.

How are people who abuse opioids getting access to them?

In Canada, there is little information regarding the source of abused prescription opioids. Information from law enforcement seems to indicate that thefts and illegal prescriptions are the main ways by which people, who abuse these types of drugs, gain access to them.

Are there statistics available on opioid drug abuse?

The 2008 Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) at www.hc-sc.gc.ca/hc-pps/drugs-drogues/stat/index-eng.php was the first national general population survey on alcohol and drug use that specifically examined the use and abuse of psychoactive pharmaceuticals, including opioid pain relievers, by Canadians. According to the survey, 21.6% of Canadians 15 years and older

reported the use of opioid pain relievers in the 12 months preceding the survey. Among users of opioid pain relievers, 1.5% (which corresponds to 0.3% of the total population) reported using them to get high.

What do I do if I suspect someone else is using my opioid prescription medication?

It is illegal to sell or give away your prescription opioid pain medication to someone else. If you suspect someone else is using your prescription, you should contact your local law enforcement authorities. To minimize the chance that someone else will access your medication, store it in a safe place, keep track of the amounts, and return any unused opioid pain medication to the pharmacy for safe disposal.

How are opioid medications regulated?

Before authorizing a drug for sale in Canada, Health Canada rigorously assesses all available scientific data to determine whether the drug's potential benefits outweigh its potential risks for the proposed indication or use.

All drugs, including opioid medications, are regulated under the *Food and Drugs Act* and the *Food and Drug Regulations* at www.hc-sc.gc.ca/fn-an/legislation/acts-lois/act-loi_reg-eng.php, which work to ensure products (including food, drugs, and therapeutic devices), are safe, effective and appropriately labelled.



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Because of their psychoactive properties (properties that affect the mind and mental processes) and their potential for abuse, opioid pain medications are also subject to the *Controlled Drugs and Substances Act* (CDSA)

<http://laws.justice.gc.ca/en/C-38.8/>.

The CDSA provides for the control of substances that can alter mental processes and that may produce harm to health and to society when diverted or abused. With the exception of authorized use all activities involving controlled substances (i.e., possession, possession for the purposes of trafficking, trafficking, importation, exportation, possession for the purposes of exportation and production) are prohibited under the CDSA.

Under the CDSA, it is illegal to:

- carry out activities related to prescription opioid pain medications without a licence, unless you are a patient with a prescription from a licensed health care provider;
- sell or even give away your prescription opioid pain medication to someone else;
- “double doctor,” which is seeking a prescription for an opioid pain medication from more than one doctor in a short period of time without telling the others.

Regulations under the CDSA also require the pharmaceutical industry (including manufacturers, wholesalers and distributors), hospital pharmacies, retail pharmacies and practitioners to submit reports to Health Canada regarding each incidence of loss and theft.

Health Canada continues to monitor the safety of drugs once they are available for sale on the Canadian market through a number of post-market surveillance activities.

Health Canada’s regulations require drug manufacturers to maintain the most up-to-date risk information for each product approved for sale in Canada, so healthcare professionals and patients can make informed decisions about appropriate treatments.

What is Health Canada doing to combat prescription drug abuse in Canada?

Canada currently has an effective legislative and regulatory framework governing all controlled substances including those in pharmaceuticals. While this framework represents an important safeguard, Health Canada recognizes that more tools are needed at the national level to coordinate the collection and analysis of information on how prescription drugs are used and/or abused at the community level.

Some of the concrete measures that Health Canada has taken to further address this issue include increasing our knowledge-base on the nature and the extent of pharmaceutical abuse in Canada through the *Canadian Alcohol and Drug Use Monitoring Survey (CADUMS)*, and working with health professionals to prevent and detect abuse and diversion. The 2008 survey was the first national general population survey on alcohol and drug use that specifically examined the abuse of psychoactive pharmaceuticals by Canadians, including opioid pain relievers. The results of this survey are a valuable benchmark for tracking the extent of this issue in Canada.

Health Canada also collects information about losses and thefts from pharmacists, practitioners, and licensed dealers, and has access to data about what drugs are being seized by law enforcement and/or the Canada Border Services Agency.

Health Canada continues to work with experts, both internationally and across the country, to keep abreast of research and surveillance activities related to pharmaceutical abuse and to collect the most current knowledge and evidence on the abuse and diversion of pharmaceuticals.

For additional information and articles on health and safety issues go to the *It's Your Health* Web section at: www.healthcanada.gc.ca/iyh

You can also call toll free at 1-866-225-0709
or TTY at 1-800-267-1245*