

PART III: CONSUMER INFORMATION

^NOXYCODONE (Oxycodone Hydrochloride Tablets)

This leaflet is part III of the "Product Monograph" published when OXYCODONE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about OXYCODONE. Contact your doctor or pharmacist if you have any questions about the drug.

Keep OXYCODONE in a safe place away from children and pets. Accidental use by a child is a medical emergency and may result in death. Never take medicine in front of small children as they will want to copy you. If a child accidentally takes OXYCODONE get emergency help right away.

Please read this before you start taking OXYCODONE tablets. Remember this information does not take the place of your doctor's instructions.

WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT OXYCODONE?

- Life-threatening breathing problems can happen because of an overdose or if the dose you are using is too high for you. Get emergency medical help immediately if you:
 - have trouble breathing, or have slow or shallow breathing
 - have a slow heartbeat
 - have severe sleepiness
 - have cold, clammy skin
 - feel faint, dizzy, confused, or cannot think, walk or talk normally
 - have a seizure
 - have hallucinations
- Take OXYCODONE exactly as described by your physician.
- Never give OXYCODONE to anyone else, even if they have the same symptoms as you have. It may harm them or even cause death.
- Tell your doctor if you (or a family member) have ever abused or been dependent on alcohol, prescription medicines or street drugs.
- Prevent theft, misuse or abuse. Keep OXYCODONE in a safe place to protect it from being stolen.
- After you stop taking OXYCODONE, you should take the unused tablets to your pharmacist to be destroyed.

ABOUT THIS MEDICATION

What the medication is used for:

OXYCODONE is an oral immediate release tablet that releases oxycodone promptly, usually requiring a dose every 6 hours to control pain.

What it does:

Oxycodone is a medicine used to treat moderate to severe pain. Oxycodone belongs to a class of drugs which is commonly referred to as opiates, opioids or narcotics and also includes codeine, fentanyl, hydromorphone and morphine.

Your pain may increase or decrease occasionally and your doctor may need to change the amount of oxycodone you take daily (daily dosage).

When it should not be used:

OXYCODONE should not be used if:

- Your doctor did not prescribe it for you;
- You are allergic to oxycodone, opioids or any other ingredient in the tablets; (see **What the non medicinal ingredients are**)
- Your pain is mild;
- Your pain can be controlled by occasional use of non-opioid painkillers;
- You have severe asthma or severe lung problems;
- You suffer from alcoholism;
- You have a head injury;
- You suffer from seizures;
- You have a condition where the small bowel does not work properly (paralytic ileus) or you have severe pain in your abdomen;
- You are taking, or have taken within the past 2 weeks, a monoamine oxidase inhibitor medications (e.g., phenelzine sulphate, tranylcypromine sulphate, moclobemide or selegiline);
- You are pregnant, in labour or breast-feeding.

OXYCODONE should be used with caution before surgery and within the first 12-24 hours after surgery.

Individuals under 18 years of age should not take OXYCODONE.

The medicinal ingredient is:

Oxycodone Hydrochloride

The nonmedicinal ingredients are:

Croscarmellose, Sodium, Dibasic Calcium Phosphate, Magnesium Stearate and Microcrystalline Cellulose. 5 mg tablets also contain FD&C Blue No. 1 Lake.

What dosage forms it comes in:

Immediate Release Tablets: 5 mg, 10 mg and 20 mg.

WARNINGS AND PRECAUTIONS

Keep OXYCODONE out of the reach of children. You should not give OXYCODONE to anyone as inappropriate use may have severe medical consequences, including death.

BEFORE you use OXYCODONE, talk to your doctor or pharmacist if you have, or had in the past any other medical conditions, especially the following ones: trouble breathing or lung problems, head injury, liver or kidney problems, adrenal gland problems, such as Addison's disease, convulsions or seizures, alcoholism, hallucinations or other severe mental problems, past or present substance abuse or drug addiction.

Tell your doctor or pharmacist if you are pregnant, plan to become pregnant, or are breastfeeding. OXYCODONE will pass through the milk and may harm the baby. OXYCODONE should not be used in patients who are pregnant or lactating.

If you are planning surgery, or about to undergo surgery, tell your doctor that you are taking OXYCODONE.

You should take the following precautions while taking OXYCODONE tablets:

- You must not consume alcohol while taking OXYCODONE, as it may increase the chance of experiencing dangerous side effects;
- Driving or other tasks requiring full alertness should not be attempted until you are sure that taking OXYCODONE does not make you drowsy;
- You must tell your doctor and pharmacist if you are taking any other over-the-counter or prescription medications - they will tell you what you should do.

Abuse, Addiction and Physical Dependence

There is a risk of abuse or addiction with all opioids. Some patients, particularly those who have abused drugs in the past, may have a higher risk of abusing or developing an addiction while taking opioids, such as OXYCODONE. Patients who have taken OXYCODONE for a period of time may develop physical dependence, and should not abruptly stop taking it. See '**Discontinuation:**' section of this leaflet.

While there are important differences between physical dependence and addiction, each is a reason for close medical supervision and honest discussions with your doctor. If you have questions or concerns about abuse, addiction or physical dependence, please tell your doctor.

INTERACTIONS WITH THIS MEDICATION

You should not take OXYCODONE if you are currently taking (or recently stopped taking) one of the medicines known as monoamine

oxidase inhibitor medications (e.g., phenelzine sulphate, tranylcypromine sulphate, moclobemide or selegiline).

Drugs that may interact with OXYCODONE include:

- Alcohol or other sedative drugs which may enhance the drowsiness caused by oxycodone;
- Other opioids, anaesthetics, sedatives, hypnotics, antidepressants, sleeping aids, phenothiazines, neuroleptics, some heart medications (e.g., beta-blockers), chloral hydrate and glutethimide;
- Antihistamines or sleep aids (these medicines could make you drowsy and depress your breathing);
- Any nonprescription, (over-the-counter) medications;
- Any herbal remedies.

PROPER USE OF THIS MEDICATION

Usual dose:

Take the dose prescribed by your doctor. OXYCODONE tablets should be taken, usually every 6 hours (with water), as directed by your doctor.

OXYCODONE can be taken with or without food.

Your dose of OXYCODONE will be clearly labelled on the medication bottle. Be sure to follow the directions on the label exactly; this is very important. Do not increase or decrease your dose without consulting your doctor. If your dosage is changed by your doctor, be sure to write it down at the time your doctor calls or sees you, and follow the new directions exactly. Review your pain regularly with your doctor to determine if you still need OXYCODONE. Be sure to use OXYCODONE only for the condition for which it was prescribed.

Discontinuation:

After you stop taking OXYCODONE you should take the unused tablets to your pharmacist to be destroyed.

Consult your doctor for instructions on how to stop this medicine slowly to avoid uncomfortable symptoms such as body aches, diarrhea, gooseflesh, loss of appetite, nausea, nervousness or restlessness, runny nose, sneezing, tremors or shivering, stomach cramps, tachycardia, trouble with sleeping, unusual increase in sweating, unexplained fever, weakness and yawning.

You should not stop taking OXYCODONE all at once if you have been taking it for more than a few days.

Reordering OXYCODONE:

A new written prescription is required from your doctor each time you need more OXYCODONE. Therefore, it is important that you contact your doctor at least three working days before your current supply runs out.

Overdose:

The most important sign of overdose is decreased breathing (abnormally slow or weak breathing), dizziness, confusion or extreme drowsiness.

If you accidentally take an overdose of OXYCODONE, call your doctor and/or your local emergency number and/or a Regional Poison Control Centre immediately, or go to a hospital emergency and take any remaining tablets and the container with you, even though you may not feel sick.

Missed Dose:

It is very important that you do not miss any doses. If you miss one dose, take it as soon as possible. However, if it is almost time for your next dose, then skip the missed dose. Do not take two doses at once, unless your doctor tells you to. If you miss several doses in succession, talk to your doctor before restarting your medication.

Do not seek additional prescriptions for this medicine from any other doctor - unless responsibility for your pain management has been transferred to another doctor.

Should your pain increase, or any other complaint develop as a result of taking OXYCODONE tell your doctor immediately.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effects you may experience are constipation, nausea, drowsiness, dizziness, vomiting, itching, headache, dry mouth, weakness and sweating. Tell your doctor about these problems if they arise. Your doctor may order a laxative and stool softener to help relieve your constipation while you are taking OXYCODONE.

If you experience any symptoms related to difficulty in breathing, such as tight chest or wheezing, fainting, or rapid heartbeat, seek immediate emergency medical assistance.

Physical dependence, abuse and withdrawal reactions have been reported. See withdrawal reactions listed within the **“Discontinuation:”** section of this leaflet.

This is not a complete list of side effects. For any unexpected effects while taking OXYCODONE, contact your doctor or pharmacist.

HOW TO STORE IT

Store between 15°C and 30°C.

Keep OXYCODONE in a secure place to prevent theft and misuse.

Do not give OXYCODONE to anyone other than the person for whom it was prescribed, since it may seriously harm them, including death.

Keep OXYCODONE under lock and out of sight and out of reach of children. Accidental ingestion by a child is dangerous and may result in death.

REPORTING SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect .

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This leaflet summarized important information about OXYCODONE. If you would like more information, talk with your doctor and/or pharmacist.

This document plus the full product monograph, prepared for health professionals, can be obtained by contacting Pro Doc Ltée at 1-800-361-8559, <http://www.prodoc.qc.ca> or info@prodoc.qc.ca.

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Last revised: February 6, 2013