

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^NOxyNEO[®]

Oxycodone Hydrochloride Controlled Release Tablets

Read this carefully before you start taking **OxyNEO** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **OxyNEO**.

Serious Warnings and Precautions

- Even if you take OxyNEO as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to overdose and death. To understand your risk of opioid addiction, abuse, and misuse you should speak to your healthcare professional.
- When you take OxyNEO it must be swallowed whole. Do not cut, break, crush, chew, or dissolve the tablets. This can be dangerous and can lead to death or seriously harm you.
- Life-threatening breathing problems can happen while taking OxyNEO, especially if not taken as directed. Babies are at risk of life-threatening breathing problems if their mothers take opioids while pregnant or nursing.
- Never give anyone your OxyNEO. They could die from taking it. If a person has not been prescribed OxyNEO, taking even one dose can cause a fatal overdose. This is especially true for children.
- If you took OxyNEO while you were pregnant, whether for short or long periods of time or in small or large doses, your baby can suffer life-threatening withdrawal symptoms after birth. This can occur in the days after birth and for up to 4 weeks after delivery. If your baby has any of the following symptoms:
 - has changes in their breathing (such as weak, difficult or fast breathing);
 - is unusually difficult to comfort;
 - has tremors (shakiness);
 - has increased stools, sneezing, yawning, vomiting, or fever.

Seek immediate medical help for your baby

- Taking OxyNEO with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

What is OxyNEO used for?

OxyNEO is used in adults to manage long-term pain, when:

- the pain is severe enough to require daily, around-the-clock pain medication; and
- the healthcare professional determines that other treatment options are not able to effectively manage your pain.

It is NOT used “as needed” to treat pain that you only have once in a while.

How does OxyNEO work?

OxyNEO is a painkiller belonging to the class of medicines known as opioids. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

What are the ingredients in OxyNEO?

Medicinal ingredient: oxycodone hydrochloride.

Non-medicinal ingredients: butylated hydroxytoluene (BHT), hypromellose, magnesium stearate, polyethylene glycol, polyethylene oxide, silicon dioxide, and titanium dioxide.

The tablet coatings contain the following additional ingredients:

- 10 mg: hydroxypropyl cellulose.
- 15 mg: black iron oxide, red iron oxide, yellow iron oxide.
- 20 mg: polysorbate 80, and red iron oxide.
- 30 mg: black iron oxide, polysorbate 80, red iron oxide, yellow iron oxide.
- 40 mg: polysorbate 80, and yellow iron oxide.
- 60 mg: black iron oxide, polysorbate 80, red iron oxide.
- 80 mg: FD&C Blue No. 2, hydroxypropyl cellulose, and yellow iron oxide.

OxyNEO comes in the following dosage forms:

Controlled Release Tablets: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, and 80 mg of oxycodone hydrochloride.

Do not use OxyNEO if:

- your healthcare professional did not prescribe it for you.
- you are allergic to oxycodone hydrochloride, or any of the other ingredients of OxyNEO.
- you have mild or short-term pain that can be controlled by the occasional use of painkillers including those available without a prescription.
- you have severe asthma, trouble breathing, or other lung problems.
- you have bowel blockage or narrowing of the stomach or intestines.
- you have a condition where the bowel does not work properly (ileus) or you have severe pain in your abdomen (for example from appendicitis or pancreatitis).
- you have increased pressure in your skull, a head injury.
- you have or have a history with epilepsy.
- you suffer from alcoholism or alcohol withdrawal.
- you are being treated for narcotic withdrawal.
- you are opioid-dependent (need to keep taking opioids to avoid withdrawal symptoms).
- you have severe kidney problems.
- you are taking, or have taken within the past 2 weeks, a monoamine oxidase inhibitor (MAOI) (such as phenelzine sulphate, tranylcypromine sulphate, moclobemide, or selegiline).
- you are pregnant or plan to become pregnant, or you are in labour and delivery.
- you are breastfeeding.
- you are going to have a surgery or operation or have had a surgery in the last 24 hours.
- you have any heart problems.
- you have severe central nervous system (CNS) depression (nervous system slows down).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take OxyNEO. Talk about any health conditions or problems you may have, including if you:

- have a history of illicit or prescription drug or alcohol abuse.
- have kidney liver or lung problems.
- have been told you are at risk of having heart problems or seizures.
- have low blood pressure.
- have a sleep disorder which causes pauses in breathing or shallow breathing while sleeping (sleep apnea).
- have past or current depression.
- have problems with your thyroid, adrenal, or prostate gland.
- suffer from chronic or severe constipation.
- have or have had problems with your mood (such as depression or anxiety), hallucinations, or other mental health problems.
- have circulatory problems (e.g., body does not get enough oxygen and nutrients to function properly due to lack of blood flow).
- have gastrointestinal (GI) problems.
- have a history of pancreas or gall bladder problems.
- are planning to breastfeed.
- are planning on drinking alcohol. Drinking alcohol while taking OxyNEO may cause dangerous side effects, including death. Do not drink alcohol while taking OxyNEO.
- have a condition that causes weakness or frailty.
- have difficulty swallowing (e.g., narrowing of the throat).
- have difficulty urinating.
- are 65 years of age and older.
- have been told that you are “opioid tolerant”. Ask your healthcare professional if you are unsure.
- have diabetes.

Other warnings you should know about:

Taking OxyNEO can cause the following serious side effects:

- **Disorder of the adrenal gland:** You may develop a disorder of the adrenal gland called adrenal insufficiency. This means that your adrenal gland is not making enough certain hormones. You may experience symptoms such as:
 - nausea, vomiting;
 - feeling tired, weak, or dizzy;
 - decreased appetite.

You may be more likely to have problems with your adrenal gland if you have been taking opioids for longer than one month. Your healthcare professional may do tests, give you another medication, and slowly take you off OxyNEO.

- **Serotonin toxicity (also known as serotonin syndrome):** OxyNEO can cause serotonin toxicity, a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles, and digestive system work. You may develop serotonin toxicity if you take OxyNEO with certain antidepressants or migraine medications.

Serotonin toxicity symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
 - muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination;
 - fast heartbeat, changes in blood pressure;
 - confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma.
- **Sleep apnea:** Opioids can cause a problem called sleep apnea (stopping breathing from time to time while sleeping). Tell your healthcare professional if you have a history of sleep apnea or if anyone notices that you stop breathing from time to time while sleeping.

See the **Serious side effects and what to do about them** table below for more information on these and other serious side effects.

Drug addiction, dependence, and tolerance: Like any opioid, if you use OxyNEO for a long time, it may cause mental and physical dependence. Oxycodone hydrochloride also has the potential to cause addiction. There are important differences between physical dependence and addiction. If you use opioids for a long time, you may develop tolerance. This means that you may need higher doses of OxyNEO to feel the same level of pain relief. It is important that you talk to your healthcare professional if you have questions or concerns about addiction, physical dependence, or tolerance. Your healthcare professional should prescribe and administer OxyNEO with the same degree of caution appropriate to the use of other oral opioid medications. It is not recommended to use these products for a long period of time.

Pregnancy, nursing, labour, and delivery: Do not use OxyNEO while pregnant, nursing, during labour or delivery. Opioids can be transferred to your baby through breast milk, or while still in the womb. OxyNEO can then cause life-threatening breathing problems in your unborn baby or nursing infant. If you become pregnant while taking OxyNEO, tell your healthcare professional right away.

If you are pregnant and are taking OxyNEO, it is important that you don't stop taking your medication all of a sudden. If you do, it can cause a miscarriage or a still-birth. Your healthcare professional will monitor and guide you on how to slowly stop taking OxyNEO. This may help avoid serious harm to your unborn baby.

Driving and using machines: Before you do tasks which may require special attention, you should wait until you know how you react to OxyNEO. OxyNEO can cause:

- drowsiness,
- dizziness, or
- light headedness.

This can usually occur after you take your first dose and when dose is increased.

Sexual function and reproduction: Long term use of opioids may lead to a decrease in sex hormone levels. It may also lead to low libido (desire to have sex), erectile dysfunction or being infertile.

Worsening pain: Taking opioids for pain can sometimes have the unintended effect of making your pain feel worse (opioid-induced hyperalgesia) even though your opioid dose has been unchanged or increased. This can also include feeling pain in new places in your body, or feeling pain from something that would not normally hurt, for example, feeling pain from clothing touching your skin. Tell your healthcare professional if you notice a change like this in your pain while you are taking OxyNEO.

Testing and check-ups: Your healthcare professional will regularly monitor your health. This includes monitoring for signs of:

- misuse and abuse;
- sleep apnea (a sleep disorder which causes pauses in breathing or shallow breathing while sleeping);
- respiratory depression and sedation (e.g., slow, shallow, or weak breathing).

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements, or alternative medicines.

Serious Drug Interactions

Serious drug interactions with OxyNEO include:

- benzodiazepines used to help you sleep or that help reduce anxiety.
- central nervous system (CNS) depressants used to slow down the nervous system. These can include:
 - other opioids and mixed opioid agonists/antagonists used to relieve pain (e.g., pentazocine, nalbuphine, butorphanol, and buprenorphine);
 - hypnotics used to help with sleeping;
 - antidepressants used for depression and mood disorders (e.g., tricyclic antidepressants; serotonin norepinephrine re-uptake inhibitors [SNRIs]; and selective serotonin re-uptake inhibitors [SSRIs] such as St. John's Wort);
 - tranquilizers, and phenothiazines used to treat mental or emotional disorders;
 - muscle relaxants used to treat muscle spasms and back pain (e.g., baclofen);
 - general anaesthetics used during surgery;
 - antipsychotics and neuroleptics used to treat mental health disorders;
 - antihistamines used to treat allergies;
 - antiemetics used to prevent nausea or vomiting;
 - sedatives which may enhance the drowsiness;
 - pregabalin, used to treat nerve pain;
 - gabapentin, used to prevent and control seizures in the treatment of epilepsy;
 - beta blockers used to lower blood pressure;
 - alcohol. This includes prescription and non-prescription medications that contain alcohol. Do not drink alcohol while you are taking OxyNEO. It can lead to drowsiness, unusually slow or weak breathing, serious side effects, or a fatal overdose.
- monoamine oxidase inhibitors (MAOIs) used to treat depression. Do not take OxyNEO with MAOIs or if you have taken MAOI's in the last 14 days.

The following may also interact with OxyNEO:

- anticoagulants used to thin the blood and prevent blood clots (e.g., warfarin and coumadin).
- medicines that can affect the heart (e.g., amiodarone and quinidine).
- medicines used to treat Parkinson's Disease.
- antibiotics used to treat bacterial infections (e.g., erythromycin, clarithromycin, rifampin).
- antifungals used to treat fungal infections (e.g., ketoconazole and voriconazole).
- antiretrovirals used to treat viral infections (e.g., ritonavir).
- anticonvulsants used to treat seizures (e.g., carbamazepine, phenytoin).
- grapefruit juice.

How to take OxyNEO:

- Take OxyNEO exactly as prescribed by your healthcare professional.
- OxyNEO must be taken orally, by mouth. Do **NOT** administer the OxyNEO tablets via any other route (e.g., via nasogastric, gastric, or other feeding tubes, or rectally) as this can cause serious harm, including death.
- OxyNEO can be taken with or without food.
- **Swallow the whole tablet. Do not cut, break, chew, dissolve, or crush OxyNEO tablets. This can be dangerous and can lead to death or seriously harm you.**
- **To reduce the chances of having difficulties swallowing:**
 - **Take one OxyNEO tablet at a time;**
 - **Do NOT pre-soak, lick, or otherwise wet the tablet prior to placing it in your mouth;**
 - **Take each tablet with enough water to ensure complete swallowing immediately after placing it in your mouth.**
- If you experience difficulty swallowing or pain in your throat or chest after taking OxyNEO, seek immediate medical attention as you may require medical assistance to remove the tablet.
- The OxyNEO 60 mg and 80 mg strength tablets will only be prescribed if you are “opioid tolerant”. Your healthcare professional will tell you when you are “opioid tolerant” to a certain dose of OxyNEO.
- Review your pain regularly with your healthcare professional to determine if you still need OxyNEO. Be sure to use OxyNEO only for the condition for which it was prescribed.

Usual dose:

Your dose is tailored/personalized just for you. Take it exactly as your healthcare professional has told you to. Do not increase or decrease your dose without consulting your healthcare professional. Taking higher doses can lead to more side effects and a greater chance of overdose.

Stopping your Medication: If you have been taking OxyNEO for more than a few days you should not stop taking it all of a sudden. Your healthcare professional will monitor and guide you on how to slowly stop taking OxyNEO. You should do it slowly to avoid uncomfortable symptoms such as having:

- body aches,
- diarrhea,
- goosebumps,
- loss of appetite,
- nausea,
- feeling nervous or restless,
- runny nose,
- sneezing,
- tremors or shivering,
- stomach cramps,
- rapid heart rate (tachycardia),
- having trouble with sleeping,
- an unusual increase in sweating,
- heart palpitations,

- an unexplained fever,
- weakness,
- yawning.

By reducing or stopping your opioid treatment, your body will become less used to opioids. If you start treatment again, you will need to start at the lowest dose. You may overdose if you restart at the last dose you took before you slowly stopped taking OxyNEO

Refilling Prescriptions for OxyNEO: A new written prescription is required from your healthcare professional each time you need more OxyNEO. Therefore, it is important that you contact your healthcare professional before your current supply runs out.

Only obtain prescriptions for this medicine from the healthcare professional in charge of your treatment. Do not seek prescriptions from other healthcare professionals unless you switch to another healthcare professional for your pain management.

Overdose:

Signs of overdose may include:

- unusually slow or weak breathing,
- dizziness,
- confusion,
- extreme drowsiness,
- shrinking of pupils,
- floppy muscles/low muscle tone,
- cold and clammy skin,
- toxic leukoencephalopathy (a brain disorder affecting the brain's white matter),
- slow heart rate,
- low blood pressure,
- sleep apnea (a sleep disorder which causes pauses in breathing or shallow breathing while sleeping),
- cardiac arrest (heart stops beating suddenly),
- pulmonary edema (build-up of fluid in the lungs),
- hypoglycemia (low blood sugar).

If you think you, or a person you are caring for, have taken too much OxyNEO, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:

It is important that you do not miss any doses. If you miss:

- **One dose:** Skip the missed dose and take your next dose as scheduled. Do not take two doses at once to make-up for the missed dose.
- **Several doses in a row:** Talk to your healthcare professional before restarting your medication.

What are possible side effects from using OxyNEO?

These are not all the possible side effects you may have when taking OxyNEO. If you experience any side effects not listed here, tell your healthcare professional.

Side effects with OxyNEO may include:

- constipation. Talk with your healthcare professional about ways to prevent constipation when you start using OxyNEO;
- dizziness;
- drowsiness;
- dry mouth;
- headache;
- itching;
- weakness, uncoordinated muscle movement;
- nausea, vomiting, or poor appetite;
- sweating;
- insomnia;
- abdominal pain;
- fever;
- diarrhea;
- indigestion;
- tremor;
- abnormal dreams or thoughts;
- anxiety;
- confusion;
- depression;
- nervousness;
- rash;
- difficulty breathing;
- low sex drive, impotence (erectile dysfunction), infertility.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Hallucinations: seeing or hearing things that are not there.			✓
Seizures (fit): uncontrollable shaking with or without loss of consciousness.			✓
RARE			
Allergic reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing.			✓
Bowel blockage (impaction): abdominal pain, severe constipation, or nausea.			✓
Fast, slow or irregular heartbeat: heart palpitations.		✓	
Hypotension (low blood pressure): dizziness, fainting, or light-headedness.	✓		
Overdose: hallucinations, confusion, inability to walk normally, slow, or weak breathing, extreme sleepiness, sedation, or dizziness, floppy muscles/low muscle tone, or cold and clammy skin.			✓
Respiratory depression: slow, shallow or weak breathing.			✓
Serotonin toxicity (also known as serotonin syndrome): a reaction which may cause feelings of agitation or restlessness, flushing, muscle twitching, involuntary eye movements, heavy sweating, high body temperature (>38°C), or rigid muscles.			✓
Withdrawal: nausea, vomiting, diarrhea, anxiety, shivering, cold and clammy skin, body aches, loss of appetite, or sweating.		✓	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNKNOWN FREQUENCY			
Disorder of the adrenal gland: nausea, vomiting, anorexia, fatigue, weakness, dizziness, or low blood pressure.			✓
Sleep apnea: stop breathing for short periods during your normal nightly sleep.		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store OxyNEO at room temperature (15° - 30°C). Keep in a dry place.
- Keep unused or expired OxyNEO in a secure place to prevent theft, misuse, or accidental exposure. It should be kept under lock, out of sight and reach of children and pets.
- Never take medicine in front of small children as they will want to copy you. Accidental ingestion by a child is dangerous and may result in death. If a child accidentally takes OxyNEO, get emergency help right away.
- OxyNEO should never be thrown into household trash, where children and pets may find it. It should be returned to a pharmacy for proper disposal.

If you want more information about OxyNEO:

- Talk to your healthcare professional
- Find the full Product Monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website <http://www.purdue.ca>, or by calling 1-800-387-4501.

This leaflet was prepared by Purdue Pharma.

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