

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

**^N
OXYCODONE-ACET**

Acetaminophen 325 mg and Oxycodone Hydrochloride 5 mg Tablets, USP

Read this carefully before you start taking **OXYCODONE-ACET** 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 **OXYCODONE-ACET**.

Serious Warnings and Precautions

- **Even if you take OXYCODONE-ACET as prescribed you are at a risk for opioid addiction, abuse and misuse. This can lead to overdose and death.**
- **When you take OXYCODONE-ACET it must be swallowed whole. Do not cut, break, crush, chew, dissolve the tablet. This can be dangerous and can lead to death or seriously harm you.**
- **You may get life-threatening breathing problems while taking OXYCODONE-ACET. This is less likely to happen if you take it as prescribed by your doctor.**
- **You should never give anyone your OXYCODONE-ACET. They could die from taking it. If a person has not been prescribed OXYCODONE-ACET, taking even one dose can cause a fatal overdose. This is especially true for children.**
- **If you took OXYCODONE-ACET 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 OXYCODONE-ACET 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 OXYCODONE-ACET used for?

OXYCODONE-ACET is a combination product that contains two medications: oxycodone hydrochloride and acetaminophen. Oxycodone - acetaminophen is used to relieve moderate to moderately severe pain, including conditions associated with fever.

How does OXYCODONE-ACET work?

OXYCODONE-ACET is a painkiller belonging to the class of drugs known as opioids. It relieves pain by acting on specific nerve cells of the spinal cord and brain. Acetaminophen belongs to the group of medications called analgesics (pain relievers) and antipyretics (fever reducers). Oxycodone belongs to the group of medications called narcotic analgesics.

What are the ingredients in OXYCODONE-ACET?

Medicinal ingredients: oxycodone and acetaminophen

Non-medicinal ingredients: Colloidal Silicon Dioxide, Lactose, Magnesium Stearate, Microcrystalline Cellulose, Povidone, Pregelatinized Starch, Sodium Starch Glycolate and Stearic Acid.

OXYCODONE-ACET comes in the following dosage forms:

Each OXYCODONE-ACET tablet contains 5 mg oxycodone hydrochloride, and 325 mg acetaminophen.

Do not use OXYCODONE-ACET if:

- Your doctor did not prescribe it for you
- Your pain is mild
- you are allergic to oxycodone hydrochloride, acetaminophen or any of the other ingredients in OXYCODONE-ACET
- you can control your pain by the occasional use of other pain medications. This includes those available without a prescription
- you have severe asthma, trouble breathing, or other breathing problems
- you have any heart problems
- you have severe liver disease
- you have bowel blockage or narrowing of the stomach or intestines
- you have severe pain in your abdomen
- you have a head injury
- you are at risk for seizures
- you suffer from alcoholism
- you are taking or have taken within the past 2 weeks a Monoamine Oxidase inhibitor (MAOi) (such as phenelzine sulphate, tranlycypromine sulphate, moclobemide or selegiline)
- you are going to have a planned surgery

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

- have a history of illicit or prescription drug or alcohol abuse. You must not consume alcohol while taking OXYCODONE-ACET, as it may increase the chance of experiencing dangerous side effects.
- you are taking any other medications, including natural health products, salicylates or other pain and fever relief medications (nonsteroidal anti-inflammatory drugs (NSAIDs)), or prescription medications
- have severe kidney disease
- are taking other products containing acetaminophen. Acetaminophen can cause decreased liver function. Taking more than the maximum daily dose of acetaminophen may cause severe or possibly fatal liver damage. People with liver disease or reduced liver function should discuss with their doctor how this medication may affect their medical condition, how their medical condition may affect the dosing and effectiveness of this medication, and whether any special monitoring is needed.
- have low blood pressure
- suffer from migraines
- have or had depression
- suffer from chronic or severe constipation
- have problems with your thyroid, adrenal or prostate gland
- have, or had in the past hallucinations or other severe mental problems
- are pregnant or planning to become pregnant or you are in labour. This medication should not be used during pregnancy unless the benefits outweigh the risks. If you become pregnant while taking this medication, contact your doctor immediately.
- are breastfeeding. This medication passes into breast milk. If you are a breast-feeding mother and are taking oxycodone and acetaminophen, it may affect your baby. Talk to your doctor about whether you should continue breast-feeding.

DO NOT take with other products containing acetaminophen. Taking more than the maximum daily dose of acetaminophen may cause severe or possibly fatal liver damage.

Serious Skin Reactions (Acute Generalized Exanthematous Pustulosis, Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis): Acetaminophen can cause serious skin reactions that can spread to your mouth, lips, face, hands, trunk, arms and legs. This condition is life-threatening.

Other warnings you should know about:

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

- drowsiness
- dizziness or
- lightheadedness

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

Children: The safety and effectiveness of using OXYCODONE-ACET have not been established in children.

Dependence and withdrawal: This medication contains oxycodone. Physical dependence, psychological dependence, and abuse have occurred with the use of oxycodone. People with a history of past or current substance use problems may be at greater risk of developing abuse or addiction while taking this medication. Abuse is not a problem with people who require this medication for pain relief. If this medication is stopped suddenly, you may experience withdrawal symptoms such as anxiety, sweating, trouble sleeping, shaking, pain, nausea, tremors, diarrhea, and hallucinations. If you have been taking this medication for a while, it should be stopped gradually as directed by your doctor.

Liver Injury: Liver injury can occur when more than the maximum daily dose of acetaminophen is taken. Follow your doctor's instructions to know how much acetaminophen you can take in a day. Acetaminophen can be in oral solutions/drops, syrup, pills, capsules, suppositories, intravenous solutions etc. To calculate how much acetaminophen you have had in a day, read the labels on all products to see if they contain acetaminophen. Keep track of how much acetaminophen is in each dose and how much you have taken in a 24 hour period.

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

The following may interact with OXYCODONE-ACET:

- Alcohol. This includes prescription and non-prescription medications that contain alcohol. **Do not** drink alcohol while you are taking OXYCODONE-ACET. It can lead to:
 - drowsiness
 - unusually slow or weak breathing
 - serious side effects or
 - a fatal overdose
- drugs used to treat migraines (e.g. triptans)
- other opioid analgesics (drugs used to treat pain)
- other medications that contain acetaminophen (including over-the-counter preparations containing acetaminophen), or oxycodone
- general anesthetics (drugs used during surgery)
- benzodiazepines (drugs used to help you sleep or that help reduce anxiety)
- antidepressants (for depression and mood disorders). **Do not** take OXYCODONE-ACET with MAO inhibitors (MAOi) or if you have taken MAOi's in the last 14 days.
- drugs used to treat serious mental or emotional disorders (such as schizophrenia)
- antihistamines (drugs used to treat allergies)
- anti-emetics (drugs used for the prevention of vomiting)
- drugs used to treat muscle spasms and back pain
- warfarin (such as Coumadin) and other anticoagulants (used for prevention or treatment of blood clots)
- anti-retroviral drugs (used to treat viral infections)
- anti-fungal drugs (used to treat fungal infections)
- antibiotic drugs (used to treat bacterial infections)

- some heart medication (such as beta blockers)
- grapefruit juice
- nonprescription, (over- the-counter) medications
- herbal remedies

How to take OXYCODONE-ACET:

Swallow whole. Do not cut, break, crush, chew or dissolve the tablet. This can be dangerous and can lead to death or seriously harm you.

Usual Adult Starting Dose:

The dosage varies according to each individual and can be affected by the severity of the pain as well as each person's response to the medication.

The usual recommended adult dose of OXYCODONE-ACET (each tablet contains 5 mg oxycodone and 325 mg acetaminophen) is one tablet every 6 hours as needed for pain. OXYCODONE-ACET is not recommended for people under 18 years of age.

Do not give this medication to anyone else, even if they have the same symptoms as you do. It can be harmful for people to take this medication if their doctor has not prescribed it.

Your dose is tailored/personalized just for you. Be sure to follow your doctor's dosing instructions exactly. Do not increase or decrease your dose without consulting your doctor.

Review your pain regularly with your doctor to determine if you still need OXYCODONE-ACET. Be sure to use OXYCODONE-ACET only for the condition for which it was prescribed.

If your pain increases or you develop any side effect as a result of taking OXYCODONE-ACET, tell your doctor immediately.

Children: The safety and effectiveness of using OXYCODONE-ACET have not been established in children.

Stopping your Medication:

This medication may be habit-forming for long periods of time. If you have been taking OXYCODONE-ACET for more than a few days you should not stop taking it all of a sudden. You should check with your doctor for directions on how to slowly stop taking it. You should do it slowly to avoid uncomfortable symptoms such as having:

- body aches
- diarrhea
- gooseflesh
- loss of appetite
- nausea
- feeling nervous or restless
- runny nose
- sneezing

- tremors or shivering
- stomach cramps
- rapid heart rate (tachycardia)
- having trouble sleeping
- an unusual increase in sweating
- an unexplained fever
- weakness
- yawning
- anxiety
- hallucinations

Refilling your Prescription for OXYCODONE-ACET:

A new written prescription is required from your doctor each time you need more OXYCODONE-ACET. Therefore, it is important that you contact your doctor before your current supply runs out.

Overdose:

If you think you have taken too much OXYCODONE-ACET, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Exceeding the recommendations by your doctor can result in respiratory depression (shallow, slow breathing), seizures, liver damage, coma, heart stoppage and death. Taking a significant overdose can result in hepatic toxicity.

Signs of overdose may include:

- unusually slow or weak breathing
- dizziness
- confusion
- extreme drowsiness
- increased sweating
- nausea
- vomiting
- stomach pain
- loss of appetite

Missed Dose:

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. If you miss several doses in succession, talk to your doctor before restarting your medication.

What are possible side effects from using OXYCODONE-ACET?

These are not all the possible side effects you may feel when taking OXYCODONE-ACET. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- Drowsiness
- Insomnia
- Dizziness
- Fainting
- Nausea, vomiting, or a poor appetite
- Dry mouth
- Headache
- Problems with vision
- Weakness, uncoordinated muscle movement
- Itching
- Sweating
- Constipation
- Mood Changes
- Sleepiness
- Low sex drive, impotence (erectile dysfunction), infertility

Talk with your doctor or pharmacist about ways to prevent constipation when you start using OXYCODONE-ACET.

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	
RARE Overdose: hallucinations, confusion, inability to walk normally, slow or weak breathing, extreme sleepiness, sedation, or dizziness, floppy muscles/low muscle tone cold and clammy skin.			✓
Respiratory Depression: Slow, shallow or weak breathing.			✓
Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
Bowel Blockage (impaction): abdominal pain, severe constipation, nausea			✓
Withdrawal: nausea, vomiting, diarrhea, anxiety, shivering, cold and clammy skin, body aches, loss of appetite, sweating.		✓	
Fast, Slow or Irregular Heartbeat: heart palpitations.		✓	

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	
Low Blood Pressure: dizziness, fainting, light-headedness.	✓		
Serotonin Syndrome: agitation or restlessness, loss of muscle control or muscle twitching, tremor, diarrhea			✓
VERY RARE Serious Skin Reactions (Acute Generalized Exanthematous Pustulosis, Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis): any combination of itchy skin rash, redness, blistering and peeling of the skin and/or of the lips, eyes, mouth, nasal passages or genitals, accompanied by fever, chills, headache, cough, body aches or joint pain, yellowing of the skin or eyes, dark urine			✓
Liver Injury: yellowing of the skin or eyes, dark urine, abdominal pain, nausea, vomiting, loss of appetite		✓	
UNKNOWN Convulsions (seizures)			✓

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

Reporting Suspected 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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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

Storage:

OXYCODONE-ACET tablets should be stored at room temperature (15 to 30°C).

Keep unused or expired OXYCODONE-ACET in a secure place to prevent theft, misuse or accidental exposure.

Keep OXYCODONE-ACET out of sight and reach of children and pets.

Disposal:

OXYCODONE-ACET 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 OXYCODONE-ACET:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this consumer medication information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada.html>); the manufacturer's website <http://www.prodoc.qc.ca> or by calling 1-800-361-8559.

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Last Revised: January 16, 2018