

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

**® Sandoz Oxycodone/Acetaminophen
oxycodone hydrochloride 5 mg and acetaminophen 325 mg Tablets**

Read this carefully before you start taking Sandoz Oxycodone/Acetaminophen 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 Sandoz Oxycodone/Acetaminophen.

Serious Warnings and Precautions

- **Even if you take Sandoz Oxycodone/Acetaminophen as prescribed, you are at a risk for opioid addiction, abuse and misuse. This can lead to overdose and death.**
- **When you take Sandoz Oxycodone/Acetaminophen, 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 Sandoz Oxycodone/Acetaminophen. This is less likely to happen if you take it as prescribed by your doctor. Babies are at risk of life-threatening breathing problems if their mothers take opioids while pregnant or nursing.**
- **You should never give anyone your Sandoz Oxycodone/Acetaminophen. They could die from taking it. If a person has not been prescribed Sandoz Oxycodone/Acetaminophen, taking even one dose can cause a fatal overdose. This is especially true for children.**
- **If you took Sandoz Oxycodone/Acetaminophen 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 Sandoz Oxycodone/Acetaminophen 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 Sandoz Oxycodone/Acetaminophen used for?

Sandoz Oxycodone/Acetaminophen is used to treat pain in adults.

How does Sandoz Oxycodone/Acetaminophen work?

Sandoz Oxycodone/Acetaminophen is a combination product that contains two medications: oxycodone and acetaminophen.

Oxycodone is a pain medication belonging to the class of drugs known as opioids which includes codeine, fentanyl, morphine and oxycodone. It relieves pain by acting on specific nerve cells of the spinal cord and brain. Acetaminophen reduces pain and fever.

What are the ingredients in Sandoz Oxycodone/Acetaminophen?

Medicinal ingredients: oxycodone and acetaminophen.

Non-medicinal ingredients: colloidal silicon dioxide, crospovidone, microcrystalline cellulose, povidone, and stearic acid.

Sandoz Oxycodone/Acetaminophen comes in the following dosage forms:

Each Sandoz Oxycodone/Acetaminophen tablet contains 5 mg oxycodone hydrochloride, and 325 mg acetaminophen.

Do not use Sandoz Oxycodone/Acetaminophen 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 Sandoz Oxycodone/Acetaminophen (see **What are the ingredients in Sandoz Oxycodone/Acetaminophen?**).
- 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 have a brain tumor.
- You suffer from alcoholism.
- 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 going to have, or recently had, a planned surgery.
- You are pregnant or planning to become pregnant or you are in labour.
- You are breastfeeding

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Sandoz Oxycodone/Acetaminophen. 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 severe kidney, liver or lung 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 heart disease.
- Have low blood pressure.
- Have past or current depression.
- Suffer from chronic or severe constipation.
- Have problems with your adrenal or prostate gland.
- Have, or had in the past hallucinations or other severe mental problems.
- Suffer from migraines.
- Are planning to become pregnant.

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:

Opioid dependence and addiction: There are important differences between physical dependence and addiction. It is important that you talk to your doctor if you have questions or concerns about abuse, addiction or physical dependence.

Pregnancy, nursing, labour and delivery:

Do not use Sandoz Oxycodone/Acetaminophen while pregnant, nursing, during labour or delivery. Opioids can be transferred to your baby through breast milk, or while still in the womb. Sandoz Oxycodone/Acetaminophen can then cause life-threatening breathing problems in your unborn baby or nursing infant.

Driving and using machines: Before you do tasks which may require special attention, you should wait until you know how you react to Sandoz Oxycodone/Acetaminophen.

Sandoz Oxycodone/Acetaminophen can cause:

- drowsiness
- dizziness or
- lightheadedness.

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

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 of 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 doctor may do tests, give you another medication, and slowly take you off Sandoz Oxycodone/Acetaminophen.

Serotonin Syndrome: Sandoz Oxycodone/Acetaminophen can cause Serotonin Syndrome, 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 Syndrome if you take Sandoz Oxycodone/Acetaminophen with certain anti-depressants or migraine medications.

Serotonin Syndrome 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.

Sexual Function/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.

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 Sandoz Oxycodone/Acetaminophen:

- Alcohol. This includes prescription and non-prescription medications that contain alcohol.

Do not drink alcohol while you are taking Sandoz Oxycodone/Acetaminophen. It can lead to:

- drowsiness
 - unusually slow or weak breathing
 - serious side effects or
 - a fatal overdose
- Other sedative drugs which may enhance the drowsiness caused by Sandoz Oxycodone/Acetaminophen.
 - 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 Sandoz Oxycodone/Acetaminophen** 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.
 - Some heart medication (such as beta blockers).
 - Drugs used to treat migraines (e.g. triptans)
 - St. John's Wort.

How to take Sandoz Oxycodone/Acetaminophen:

Take **Sandoz Oxycodone/Acetaminophen** tablets:

- usually every 4 to 6 hours, or as directed by your doctor.
- with a full glass of water

Sandoz Oxycodone/Acetaminophen tablets:

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:

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.

Your doctor will prescribe the lowest dose that works to control your pain. It is recommended that you only take Sandoz Oxycodone/Acetaminophen for up to 7 days. If you need to take Sandoz Oxycodone/Acetaminophen for longer, your doctor will determine the best dose for you to lower the risk of side effects and overdose. Higher doses can lead to more side effects and a greater chance of overdose.

Review your pain regularly with your doctor to determine if you still need Sandoz

Oxycodone/Acetaminophen.

Be sure to use Sandoz Oxycodone/Acetaminophen only for the condition for which it was prescribed.

If your pain increases or you develop any side effect as a result of taking Sandoz Oxycodone/Acetaminophen, tell your doctor immediately.

Stopping your Medication

If you have been taking Sandoz Oxycodone/Acetaminophen for more than a few days you should not stop taking it all of a sudden. Your doctor will monitor and guide you on how to slowly stop taking Sandoz Oxycodone/Acetaminophen. 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 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 Sandoz Oxycodone/Acetaminophen.

Refilling your Prescription for Sandoz Oxycodone/Acetaminophen:

A new written prescription is required from your doctor each time you need more Sandoz Oxycodone/Acetaminophen. Therefore, it is important that you contact your doctor before your current supply runs out.

Only obtain prescriptions for this medicine from the doctor in charge of your treatment. Do not

seek prescriptions from other doctors unless you switch to another doctor for your pain management.

Overdose:

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

Signs of overdose may include:

- unusually slow or weak breathing
- dizziness
- confusion
- extreme drowsiness

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 a row, talk to your doctor before restarting your medication.

What are possible side effects from using Sandoz Oxycodone/Acetaminophen?

These are not all the possible side effects you may feel when taking Sandoz Oxycodone/Acetaminophen. 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
- Light headedness
- Sweating
- Constipation
- Low sex drive, impotence (erectile dysfunction), infertility

Talk with your doctor or pharmacist about ways to prevent constipation when you start using Sandoz Oxycodone/Acetaminophen.

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.		✓	
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			✓

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	
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.

<p>Reporting Side Effects</p> <p>You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> • Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or • Calling toll-free at 1-866-234-2345. <p><i>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.</i></p>
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Storage:

- **Keep unused or expired Sandoz Oxycodone/Acetaminophen in a secure place to prevent theft, misuse or accidental exposure.**
- Store tablets at room temperature (15 to 30°C). Keep in a dry place.
- **Keep Sandoz Oxycodone/Acetaminophen 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 Sandoz Oxycodone/Acetaminophen, get emergency help right away

Disposal:

Sandoz Oxycodone/Acetaminophen 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 Sandoz Oxycodone/Acetaminophen:

- 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/drugproducts/drug-product-database.html>); the manufacturer's website www.sandoz.ca or by calling 1-800-361-3062.

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