

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### **TARGIN®**

#### **Oxycodone Hydrochloride/Naloxone Hydrochloride Controlled Release Tablets**

Read this carefully before you start taking **TARGIN** 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 **TARGIN**.

#### **Serious Warnings and Precautions**

- Even if you take TARGIN as prescribed you are at risk for opioid addiction, abuse, and misuse. This can lead to overdose and death. To understand your risk of opioid addiction, abuse, and misuse, you should speak to your healthcare professional.
- Life-threatening breathing problems can happen while taking TARGIN, 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 TARGIN. They could die from taking it. If a person has not been prescribed TARGIN, taking even one dose can cause a fatal overdose. This is especially true for children.
- If you took TARGIN 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;get immediate medical help for your baby.
- Taking TARGIN 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.
- TARGIN tablets must be swallowed whole. Do NOT cut, break, crush, chew or dissolve the tablets as it can lead to a fatal dose of oxycodone.

#### **What is TARGIN used for?**

TARGIN 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.

TARGIN is also used to lessen the effect of constipation from opioid pain medication treatment.

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

### **How does TARGIN work?**

TARGIN is a combination of oxycodone and naloxone.

Oxycodone 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.

Naloxone is a medicine used to prevent opioid medications from binding to receptors in the gastrointestinal tract, helping reduce constipation.

### **What are the ingredients in TARGIN?**

Medicinal ingredients: Oxycodone hydrochloride and naloxone hydrochloride.

Non-medicinal ingredients: Ethylcellulose, FD&C Blue No. 1 (5/2.5 mg only), hydroxypropylcellulose (5/2.5 mg only), iron oxide (20/10 mg and 40/20 mg only), lactose monohydrate, magnesium stearate, polyethylene glycol, polyvinyl alcohol, povidone K30 (10/20 mg, 20/40 mg, and 40/20 mg only), stearyl alcohol, talc, and titanium dioxide.

### **TARGIN comes in the following dosage forms:**

Controlled Release Tablets: 5/2.5 mg, 10/5 mg, 20/10 mg, and 40/20 mg of oxycodone hydrochloride and naloxone hydrochloride.

### **Do not use TARGIN if:**

- your healthcare professional did not prescribe it for you.
- you are allergic to oxycodone hydrochloride, naloxone hydrochloride, other opioids, or any of the other ingredients in TARGIN.
- you have mild or short-term pain that can be controlled by the occasional use of pain medications, including those available without a prescription.
- you have severe asthma, trouble breathing, or other lung problems.
- you have a heart condition called cor pulmonale (right-sided heart failure).
- you have bowel blockage or narrowing of the stomach or intestines.
- you have appendicitis or a problem with your pancreas called pancreatitis.
- you have a condition where the bowel does not work properly (ileus) or you have severe pain in your abdomen.
- you have increased pressure in your skull or have a head injury.
- you have epilepsy (seizures) or a history with epilepsy.
- you have moderate to severe liver problems.
- 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 are pregnant or plan to become pregnant or you are in labour.

- you are breast-feeding.
- you are taking, or have taken within the past 2 weeks, monoamine oxidase (MAO) inhibitors used to treat depression.
- you are going to have a surgery, or recently had a surgery in the last 24 hours.
- you have severe kidney problems.
- you have severe central nervous system (CNS) depression (nervous system slows down).
- you need to receive TARGIN via a rectal route. TARGIN is only for oral administration.

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

- have kidney, liver, or lung problems.
- have heart problems.
- have low blood pressure.
- a sleep disorder which causes pauses in breathing or shallow breathing while sleeping.
- have a history of illicit or prescription drug or alcohol abuse.
- have problems with your thyroid, adrenal, or prostate gland.
- have or have had problems with your mood (such as depression or anxiety), hallucinations, or other mental health problems.
- suffer from migraines.
- are planning to become pregnant.
- are planning to breast-feed.
- have cancer.
- have a condition that causes weakness or frailty.
- have bile duct or gallbladder problems.
- have difficulty urinating.
- have been told that you are “opioid tolerant”. Ask your healthcare professional if you are unsure.

**Other warnings you should know about:**

**Taking TARGIN 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 TARGIN.

- **Serotonin toxicity (also known as serotonin syndrome):** TARGIN 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 TARGIN with certain anti-depressants 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 (pauses in breathing or shallow breathing 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 TARGIN 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 TARGIN 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 TARGIN 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 TARGIN while pregnant, nursing, during labour or delivery. Opioids can be transferred to your baby through breast milk, or while still in the womb. TARGIN can then cause life-threatening breathing problems in your unborn baby or nursing infant. If you become pregnant while taking TARGIN, tell your healthcare professional right away.

If you are pregnant and are taking TARGIN, 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 TARGIN. 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 TARGIN. TARGIN can cause:

- drowsiness,
- dizziness, or
- light headedness.

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

**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.

**Worsened 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 TARGIN.

**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

Taking TARGIN with the following medicines can cause serious side effects, including breathing problems that can lead to death:

- alcohol, including prescription and non-prescription medications that contain alcohol. Do NOT drink alcohol while you are taking TARGIN. It can lead to:
  - drowsiness;
  - depressed breathing;
  - unusually slow or weak breathing;
  - serious side effects; or
  - a fatal overdose.
- antidepressants, medicines used to treat depression (e.g., tricyclic antidepressants, polycyclic antidepressants, selective serotonin re-uptake inhibitors (SSRIs), serotonin norepinephrine re-uptake inhibitors (SNRIs)), and St. John's Wort).
- antiemetics, medicines used to prevent nausea or vomiting.
- antiepileptics, medicines used to prevent and control seizures (e.g., carbamazepine, phenytoin, and gabapentinoids such as pregabalin).
- antihistamines, medicines used to treat allergies.
- beta-blockers, medicines used to lower blood pressure.
- general anesthetics, medicines used during surgery.
- medicines used to help with sleep or that help reduce anxiety (e.g., benzodiazepines, sleep aids, tranquilizers, and hypnotics).
- medicines used to treat mental health or emotional disorders (e.g., phenothiazines, neuroleptics, antipsychotics, and anxiolytics).
- monoamine oxidase (MAO) inhibitors, medicines used to treat depression. Do NOT take TARGIN with MAO inhibitors or if you have taken MAO inhibitors in the last 14 days.
- muscle relaxants, medicines used to treat muscle spasms and back pain (e.g., baclofen).
- other opioids, medicines used to treat pain (e.g., pentazocine, nalbuphine, butorphanol, and buprenorphine).

**The following may also interact with TARGIN:**

- antibiotics, medicines used to treat bacterial infections (e.g., erythromycin, clarithromycin, rifampin).
- anticholinergics, medicines used for asthma, urinary incontinence, stomach cramps and muscle spasms.

- anticoagulants, medicines used to prevent or treat blood clots (e.g., warfarin, coumadin).
- antifungals, medicines used to treat fungal infections (e.g., ketoconazole and voriconazole).
- antiretrovirals, medicines used to treat HIV/AIDS (e.g., ritonavir).
- medicines used to treat irregular heart rhythms (e.g., amiodarone and quinidine).
- medicines used to treat Parkinson's disease.
- grapefruit juice.

### How to take TARGIN:

- Take TARGIN tablets exactly as directed by your healthcare professional.
- TARGIN tablets are designed to work properly over 12 hours when swallowed whole.
- TARGIN must be taken orally, by mouth. Do NOT take TARGIN via any other route as this may increase the risk of severe withdrawal effects.
- **Swallow the TARGIN tablets whole. Do not cut, break, chew, dissolve or crush TARGIN tablets before swallowing. This can lead to the release and absorption of an excessive dose of oxycodone which can seriously harm you.**
- TARGIN can be taken with or without food.
- Take TARGIN with sufficient fluid (e.g., 4 to 6 oz. of water) to treat pain and assist with decreasing constipation.
- You may see tablets in your stools (bowel movements) when using TARGIN. Do not be concerned, your body has absorbed the medicine.
- **Do not take the 40/20 mg strength or a single dose of 80/40 mg or more of TARGIN unless you are “opioid tolerant”. Your healthcare professional will tell you when you are “opioid tolerant” to a certain dose of TARGIN.**

### Usual Dose:

Dosage is individualized. Be sure to follow your healthcare professional’s dosing instructions exactly. 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.

The usual initial adult dose for patients who have not previously received opioid analgesics is TARGIN 10/5 mg every 12 hours. **The maximum daily dose of TARGIN should be limited to 80/40 mg/day or 40/20 mg every 12 hours.** If you need a higher dose, your healthcare professional may give you an additional oxycodone preparation without naloxone.

Review your pain regularly with your healthcare professional to determine if you still need TARGIN. Be sure to use TARGIN only for the condition for which it was prescribed.

Should your pain increase or any other complaint as a result of taking TARGIN, tell your healthcare professional immediately.

### Stopping your Medication:

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

Your healthcare professional will monitor and guide you on how to slowly stop taking TARGIN. 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 TARGIN.

#### **Refilling Prescriptions for TARGIN:**

A new written prescription is required from your healthcare professional each time you need more TARGIN. 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:

- confusion;
- dizziness;
- extreme drowsiness;
- unusually slow or weak breathing;
- shrinking or widening of the pupils;
- floppy muscles/low muscle tone;
- cold and clammy skin;
- slow heart rate;
- low blood pressure;
- muscle weakness, cramping, or aching;
- cardiac arrest (heart stops beating suddenly).

If you think you, or a person you are caring for, have taken too much TARGIN, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

It is important that you do not miss any doses. If you miss a dose, take your next dose at your usual scheduled time. You should always try to get back on track with your regular dosing schedule (e.g., 8 o'clock in the morning and 8 o'clock in the evening). If you miss several doses in a row, talk to your healthcare professional before restarting your medication.

**What are possible side effects from using TARGIN?**

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

Side effects may include:

- nausea and/or vomiting;
- constipation;
- diarrhea;
- sweating;
- fatigue;
- headache;
- dizziness;
- 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	
<b>RARE</b>			
<b>Allergic reaction:</b> itchy, red, painful, and irritated or swollen skin (rash), outbreak of pale red bumps or welts on the skin that appear suddenly (hives), swelling of the face, lips, tongue or throat, difficulty swallowing, or difficulty breathing.			✓
<b>Bowel blockage (impaction):</b> abdominal pain, severe constipation, or nausea.			✓
<b>Fast, slow or irregular heartbeat:</b> heart palpitations.		✓	
<b>Hypotension (low blood pressure):</b> dizziness, fainting, or light-headedness.	✓		
<b>Overdose:</b> hallucinations, confusion, inability to walk normally, slow or weak breathing, extreme sleepiness, sedation, dizziness, floppy muscles/low muscle tone, or cold and clammy 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	
<b>Respiratory depression:</b> slow, shallow, or weak breathing.			✓
<b>Serotonin toxicity (also known as serotonin syndrome):</b> 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.			✓
<b>Withdrawal:</b> nausea, vomiting, diarrhea, anxiety, shivering, cold and clammy skin, body aches, loss of appetite, or sweating.		✓	
<b>UNKNOWN FREQUENCY</b>			
<b>Disorder of the adrenal gland:</b> nausea, vomiting, anorexia, fatigue, weakness, dizziness, or low blood pressure.			✓
<b>Sleep apnea:</b> 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.

<p><b>Reporting Side Effects</b></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"> <li>• Visiting the Web page on Adverse Reaction Reporting (<a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html</a>) for information on how to report online, by mail or by fax; or</li> <li>• Calling toll-free at 1-866-234-2345.</li> </ul> <p><i>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.</i></p>
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**Storage:**

- Store TARGIN at room temperature (15° - 30°C). Keep in a dry place. Protect from light, heat, and humidity.

- Keep unused or expired TARGIN in a secure place to prevent theft, misuse or accidental exposure.
- Keep TARGIN 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 TARGIN, get emergency help right away.

**Disposal:** TARGIN 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 TARGIN:**

- 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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