

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

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 that can lead to overdose and death. To understand your risk of opioid addiction, abuse, and misuse you should speak to your prescriber (e.g., doctor).
- 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 feverSeek 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.

What is TARGIN used for?

TARGIN is used for the long-term management of pain, when:

- the pain is severe enough to require daily, around-the-clock pain medication
- the doctor 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?

As its active substances, TARGIN contains oxycodone and naloxone.

Oxycodone is a pain medication belonging to the class of medicines known as opioids which includes codeine, fentanyl, morphine and hydromorphone. 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, to help 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 and 40/20 mg only), lactose monohydrate, magnesium stearate, polyethylene glycol, polyvinyl alcohol, povidone K30 (10/20, 20/40 and 40/20 mg only), stearyl alcohol, talc, 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

Do not use TARGIN if:

- your doctor did not prescribe it for you
- you are allergic to oxycodone hydrochloride, naloxone hydrochloride, other opioids, or any of the other ingredients of 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 condition where the small bowel does not work properly (paralytic ileus) or you have severe pain in your abdomen
- you have a head injury
- you are at risk for seizures
- you have moderate to severe liver dysfunction
- you suffer from alcoholism
- you are being treated for narcotic withdrawal
- you are pregnant or plan to become pregnant or you are in labour
- you are breast-feeding
- you are under 18 years of age
- you take monoamine oxidase (MAO) inhibitors or if you have taken MAO inhibitors in the last 14 days before treatment with TARGIN.
- you are going to have, or recently had, a planned surgery

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 severe kidney, liver, or lung disease
- have heart disease
- have low blood pressure
- have a history of sleep apnea
- have a history of illicit or prescription drug or alcohol abuse

- have past or current depression
- have problems with your thyroid, adrenal or prostate gland
- have, or had in the past hallucinations or other severe mental problems
- suffer from migraines
- are planning to become pregnant

Other warnings you should know about:

TARGIN should not be administered rectally due to the possible increased systemic availability of naloxone by this route and the potential for the occurrence of severe withdrawal effects.

You may see tablets in your stools (bowel movements) when using TARGIN. Do not be concerned, your body has absorbed the medicine.

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 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.

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
- light headedness

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

Serotonin syndrome

TARGIN 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 TARGIN 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.

Sleep Apnea

Opioids can cause a problem called sleep apnea (stopping breathing from time to time while sleeping). Tell your doctor if you have a history of sleep apnea or if anyone notices that you stop breathing from time to time while sleeping.

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 TARGIN:

- alcohol, including prescription and non-prescription medications containing alcohol. **Do not** drink alcohol while taking TARGIN. It can lead to:
 - drowsiness
 - depressed breathing
 - unusually slow or weak breathing
 - serious side effects or
 - a fatal overdose
- other sedative drugs which may enhance the drowsiness caused by TARGIN
- other opioid analgesics (for pain)
- general anesthetics (used during surgery)
- drugs used to help you sleep or to reduce anxiety
- most antidepressants (for depression and mood disorders)
- drugs used to treat serious mental or emotional disorders such as schizophrenia
- antihistamines (for allergies)
- anticholinergics (for asthma, incontinence, gastrointestinal cramps and muscular spasms)
- anti-emetics (for prevention of vomiting)
- drugs used to treat muscle spasms and back pain
- some heart medication (beta blockers)
- warfarin and other coumarin anticoagulants (for prevention/treatment of blood clots)
- anti-retroviral, azole-anti-fungal and macrolide-antibiotic drugs
- grapefruit juice
- St. John's Wort

How to take TARGIN:

TARGIN tablets are designed to work properly over 12 hours when swallowed whole.

Swallow whole. Do not cut, break, chew, dissolve or crush TARGIN tablets before swallowing since this can lead to the release and absorption of an excessive dose of oxycodone which can seriously harm you.

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 doctor will tell you when you are “opioid tolerant” to a certain dose of TARGIN.

TARGIN can be taken with or without food with sufficient fluid (e.g., 4 to 6 oz. of water), to treat pain and assist with decreasing constipation.

Do not use for rectal administration.

Usual Dose:

Dosage is individualized. Be sure to follow your doctor's dosing instructions exactly. Do not increase or decrease your dose without consulting your doctor. 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 doctor may give you an additional oxycodone preparation without naloxone.

Review your pain regularly with your doctor 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 doctor 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 doctor 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 doctor each time you need more TARGIN. 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 TARGIN, 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:

It is important that you do not miss any doses. If you miss a dose, take your next dose at your usual 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 doctor before restarting your medication.

What are possible side effects from using TARGIN?

These are not all the possible side effects you may feel when taking TARGIN. If you experience any side effects not listed here, contact 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	
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			✓

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 (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) 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 TARGIN in a secure place to prevent theft, misuse or accidental exposure.**
- Store at room temperature (15° - 30°C). Keep in a dry place. **Protect from light, heat and**

humidity.

- 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 (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer's website <http://www.purdue.ca>, or by calling 1-800-387-4501.

This leaflet was prepared by Purdue Parma

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