

TARGIN[®] tablets

Oxycodone hydrochloride and naloxone hydrochloride dihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about TARGIN tablets.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What TARGIN tablets are taken for

TARGIN tablets contain two different medicines called oxycodone hydrochloride and naloxone hydrochloride dihydrate. Oxycodone belongs to a group of medicines called opioid analgesics. Naloxone is a medicine which, when taken orally, can block some of the effects of opioids in the gut, such as constipation.

TARGIN tablets are used to relieve moderate to severe persistent pain when other forms of treatment have not been effective and naloxone in TARGIN tablets will help prevent and treat opioid-induced constipation. Opioid analgesics such as oxycodone hydrochloride have been used to treat pain for many years.

Your doctor, however, may prescribe it for another purpose.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

As with all strong painkillers, your body may become used to you taking TARGIN tablets. Taking it may result in physical dependence.

Physical dependence means that you may experience withdrawal symptoms if you stop taking oxycodone suddenly, so it is important to take it exactly as directed by your doctor.

This medicine is only available with a doctor's prescription.

Before you take it

When you must not take it

Do not take TARGIN tablets if you:

- have moderate or severe liver problems or disease
- suffer from shallow breathing or have any other breathing problems such as severe asthma, chronic bronchitis or severely impaired lung function
- are severely drowsy or have a reduced level of consciousness
- have a condition where the small bowel does not work properly or have delayed stomach emptying
- have severe abdominal pain with bloating, cramps, vomiting or constipation
- have heart problems or disease including changes in the way the heart beats

- have had a head injury, a brain tumour or have raised pressure within the head, brain or spinal cord
- suffer from uncontrolled convulsions, fits or seizures
- have a high level of carbon dioxide or a low level of oxygen in the blood
- regularly drink large amounts of alcohol or have confusion and shaking due to stopping drinking alcohol
- take medicine for depression called a 'monoamine oxidase inhibitor' or have taken any in the last two weeks.

Do not take TARGIN tablets if you are allergic to oxycodone, naloxone, opioid painkillers, or any of the ingredients listed at the end of this leaflet.

Do not take this medicine after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work very well.

Do not take it if the packaging is torn or shows signs of tampering.

Do not take this medicine if you are pregnant or intend to become pregnant whilst taking this medicine.

Like most medicines of this kind, TARGIN tablets are not recommended to be taken during pregnancy. Your doctor will discuss the risks and benefits of using it if you are pregnant.

Do not breast-feed if you are taking this medicine.

The active ingredients in TARGIN tablets may pass into breast milk and

there is a possibility that your baby may be affected. Your doctor can discuss with you the risks and benefits involved.

Do not give this medicine to a child younger than 12 years of age.

Safety and effectiveness in children younger than 12 years of age have not been established.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- chronic kidney, mild or chronic liver or chronic lung problems
- high or low blood pressure including low blood volume causing very low blood pressure
- problems with your circulation
- underactive thyroid gland
- bile duct disease or inflammation of the pancreas
- inflammatory bowel disease
- increased prostate size
- adrenal glands not working properly
- are about to have an operation or have just had one within the last 24 hours including an operation on your spine for pain relief
- galactose intolerance, lactose deficiency or glucose-galactose malabsorption
- some cancers of the digestive tract or pelvis
- severe mental condition in which the person loses contact with reality and is unable to think and judge clearly
- an addiction or history of abuse of alcohol, opioids or other drugs.

Tell your doctor if you have used an opioid before.

Using TARGIN tablets after using higher doses of other opioids may lead to withdrawal symptoms.

If you have not told your doctor about any of the above, tell them before you take any TARGIN tablets.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines, alcohol and TARGIN tablets may interfere with each other. These medicines include:

- other pain relievers including other opioids
- medicines used to help you sleep
- medicines used to treat depression, psychiatric or mental disorders
- medicines used to prevent or relieve the symptoms of allergy
- medicines to stop nausea or vomiting e.g. metoclopramide or prochlorperazine
- cimetidine, a medicine used to treat ulcers
- medicines used to put you to sleep during an operation or procedure
- medicines used to treat depression belonging to a group called monoamine oxidase inhibitors. They should be stopped 14 days before TARGIN tablets are taken.
- medicines used to thin the blood e.g. coumarin derivatives such as warfarin
- medicines used to lower blood pressure
- quinidine and other medicines used to treat the heart
- ketoconazole, a medicine used to treat fungal infections
- medicines used to relieve stomach cramps or spasms, to prevent travel sickness or to treat Parkinson's disease
- medicines used to relax muscles.

These medicines or alcohol may be affected by TARGIN tablets or may affect how well it works. You may need to use different amounts of your medicines, or take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking this medicine.

How to take TARGIN tablets

How much to take

Your doctor will tell you exactly how much to take.

Follow the instructions given to you by your doctor or pharmacist exactly.

How to take it

Swallow TARGIN tablets whole with a full glass of water.

Do not chew, crush, break or dissolve the tablets.

TARGIN tablets are only designed to work properly if swallowed whole. The tablets may release all their contents at once if chewed, crushed, broken or dissolved which can be dangerous and cause serious problems, such as an overdose or even death.

If you have trouble swallowing your tablets whole, talk to your doctor.

You must only take TARGIN tablets by mouth.

Taking this medicine in a manner other than that prescribed by your doctor can be harmful to your health.

When to take it

Take TARGIN tablets every 12 hours.

Taking them at the same time each day will have the best effect and will mean that the onset of pain is prevented. If however, you begin to experience pain ('breakthrough pain') and you are taking your TARGIN

tablets as prescribed, contact your doctor as your dosage may need to be reviewed.

You may take this medicine with or without food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

If you stop taking this medicine suddenly, your pain may worsen and you may experience withdrawal symptoms such as:

- body aches
- loss of appetite, nausea, stomach pain or diarrhoea
- fast heart rate
- sneezing or runny nose
- chills, tremors, shivering or fever
- trouble with sleeping
- increased sweating and yawning
- weakness
- nervousness or restlessness.

If you forget to take it

If you forget to take your tablets, take your next dose as soon as you remember, unless it is almost time for your next dose, then go on as before.

Do not take a double dose to make up for the dose that you missed.

This will increase the chance of you getting unwanted side effects.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your tablets, ask your pharmacist for some hints.

For example, take your medicine at the same time each morning and evening such as 8 a.m. and 8 p.m.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia: telephone 13 11 26, New Zealand: telephone 0800 POISON or 0800 764 766) for

advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too many TARGIN tablets.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone numbers for these places handy.

You should also follow the above steps if someone other than you has taken the tablets that were prescribed for you.

If someone takes an overdose they may experience difficulties in breathing, become drowsy and tired, have constricted pupils, become confused, have very low blood pressure or slow heart rate, and may even become unconscious or die.

When seeking medical attention, take this leaflet and any remaining tablets with you to show the doctor. Also report any other medicines or alcohol which have been taken.

While you are taking it

Things you must do

Take TARGIN tablets exactly as your doctor has prescribed.

If you are about to start any new medicine, remind your doctor and pharmacist that you are taking TARGIN tablets.

Tell any other doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Tell your doctor if your pain is getting worse, or if you are having more frequent breakthrough pain.

Also tell your doctor if you are having any problems or difficulties while you are being treated with TARGIN tablets.

Tolerance to oxycodone may develop which means that the effect of the medicine may decrease. If this happens, speak to your doctor. Keep enough TARGIN tablets with you to last over weekends and holidays.

Things you must not do

Do not drink alcohol while you are taking TARGIN tablets.

Alcohol use could increase serious side effects of oxycodone, such as sleepiness, drowsiness, and slow or shallow breathing.

Do not take TARGIN tablets to treat any other complaint unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor.

Over time your body may become used to you taking oxycodone so if you stop taking it suddenly, your pain may worsen and you may have unwanted side effects such as withdrawal symptoms. This is called physical dependence.

If you need to stop taking this medicine, your doctor will gradually reduce the amount you take each day, if possible, before stopping the medicine completely.

Things to be careful of

Do not drive or operate machinery until you know how TARGIN tablets affect you.

TARGIN tablets may cause drowsiness, dizziness, hallucinations, disorientation, blurred vision or other

vision problems or may affect alertness. Discuss these aspects and any impact on your driving or operating machinery with your doctor.

Be careful if you are elderly, unwell or taking other medicines.

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness which may increase the risk of a fall.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Tell your doctor if you suffer from nausea or vomiting when taking TARGIN tablets.

If you vomit after your dose, your pain may come back, as you will not have absorbed your medicine. If this happens, speak to your doctor. Your doctor may prescribe some medicine to help you stop vomiting.

Do not be alarmed if you see remnants of the tablet in your stool.

The active substances have already been released in the stomach and gut, and absorbed into your body.

There is potential for abuse of oxycodone and the development of addiction to oxycodone. It is important that you discuss this issue with your doctor.

Be aware that TARGIN tablets may produce a positive result in sports agency drug testing procedures.

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time they are not. As for many other medicines of this type, that is opioid analgesics, many side effects tend to

reduce over time. This means that the longer you take this medicine, the less it may cause problems for you. Your doctor has weighed the risks of this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking TARGIN tablets.

This medicine helps most people with moderate to severe pain, but it may have unwanted side effects in a few people. Other side effects not listed here may also occur in some people.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- mild abdominal problems such as diarrhoea, feeling sick (nausea), loss of appetite, constipation, dry mouth, hiccups, sore throat or funny voice
- trouble sleeping, feeling anxious, nervousness, unusual thoughts or dreams or feeling deep sadness
- trouble with your balance
- sweating
- restlessness
- muscle problems such as spasms, twitching or aching
- chills, tremors, shivering or fever.

Tell your doctor as soon as possible if you notice any of the following and they worry you:

- stomach discomfort, vomiting, indigestion or abdominal pain
- abnormal thinking or changes in mood
- headache or confusion
- drowsiness, fainting or dizziness especially when standing up
- unusual weakness, loss of strength or trouble walking

- changes in taste
- generally feeling unwell
- change in passing urine such as the volume passed, pain or the feeling of needing to urinate urgently.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- you have an allergic reaction: shortness of breath, wheezing, shallow or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin
- chest pain or chest tightness
- fast or irregular heart beats
- seizures, fits or convulsions.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking it

Storage

Keep your tablets in the blister pack until it is time to use them.

If you take the tablets out of the blister pack they may not keep as well.

Keep your tablets in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink or on a window sill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking the tablets or the tablets have passed their expiry date, return any unused medicine to your pharmacist.

Product description

What it looks like

TARGIN® tablets are oblong, film-coated tablets. They are available in four strengths which are as follows:

5/2.5 mg - blue, marked "OXN" on one side and "5" on the other

10/5 mg - white, marked "OXN" on one side and "10" on the other

20/10 mg - pink, marked "OXN" on one side and "20" on the other

40/20 mg - yellow, marked "OXN" on one side and "40" on the other.

TARGIN tablets come in boxes containing blister packs of 20 and 28 tablets.

Packs of 20 tablets will only be available until current stocks are depleted.

Ingredients

Active ingredients:

- 5/2.5 mg contains 5 mg oxycodone hydrochloride and naloxone hydrochloride dihydrate equivalent to naloxone hydrochloride anhydrous 2.5 mg
- 10/5 mg contains 10 mg oxycodone hydrochloride and naloxone hydrochloride dihydrate equivalent to naloxone hydrochloride anhydrous 5 mg
- 20/10 mg contains 20 mg oxycodone hydrochloride and naloxone hydrochloride dihydrate

equivalent to naloxone hydrochloride anhydrous 10 mg

- 40/20 mg contains 40 mg oxycodone hydrochloride and naloxone hydrochloride dihydrate equivalent to naloxone hydrochloride anhydrous 20 mg.

Inactive ingredients (5/2.5mg):

- lactose
- hydroxypropylcellulose
- ethylcellulose
- stearyl alcohol
- talc
- magnesium stearate
- polyvinyl alcohol
- titanium dioxide
- macrogol 3350.

Inactive ingredients (10/5mg, 20/10mg, 40/20mg):

- lactose
- povidone
- ethylcellulose
- stearyl alcohol
- talc
- magnesium stearate
- polyvinyl alcohol
- titanium dioxide
- macrogol 3350.

In addition, the tablets also contain the colourants listed below:

- 5/2.5 mg - E133 (brilliant blue)
- 20/10 mg - E172 (iron oxide red)
- 40/20 mg - E172 (iron oxide yellow).

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer / Sponsor

TARGIN tablets are made in the UK and supplied in Australia by:

Mundipharma Pty Limited

ACN 081 322 509

50 Bridge Street

Sydney NSW 2000

Phone: 1800 188 009

TARGIN tablets are made in the UK and supplied in New Zealand on behalf of Mundipharma New Zealand Limited by:

Pharmaco (NZ) Ltd

PO BOX 4079

Auckland 1140

Phone: (09) 377-3336

Medical enquiries: 0800 773 310

®: TARGIN is a Registered Trademark.

This leaflet was updated in March 2011.

Australian Registration Numbers for TARGIN tablets are:

5/2.5 mg - AUST R 156067

10/5 mg - AUST R 156145

20/10 mg - AUST R 156189

40/20 mg - AUST R 156194