Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:
1. What Targin tablets are and what they are used for
2. What you need to know before you take Targin tablets
3. How to take Targin tablets
4. Possible side effects
5. How to store Targin tablets
6. Contents of the pack and other information

1. **What Targin tablets are and what they are used for**

You have been prescribed Targin tablets for the treatment of severe pain, which can be adequately managed only with opioid analgesics. Naloxone is added to counteract constipation.

**How Targin tablets work.**

These tablets contain oxycodone hydrochloride and naloxone hydrochloride as active substances. Oxycodone is responsible for the painkilling effect of the tablets. It is a strong analgesic (‘painkiller’) that belongs to a group of medicines called opioids. Naloxone is intended to bring relief from constipation. Constipation is a typical side effect of treatment with strong painkillers.

These are prolonged-release tablets. This means that the active ingredients are slowly released from the tablets over a period of 12 hours.

2. **What you need to know before you take Targin tablets**

**Do not take Targin tablets**

- if you are allergic (hypersensitive) to oxycodone or naloxone, or any of the other ingredients of the tablets (listed in section 6);
- if you have breathing problems, such as breathing more slowly or weakly than expected (respiratory depression);
- if you suffer from a severe lung disease associated with narrowing of the airways (chronic obstructive pulmonary disease or COPD);
- if you suffer from a condition known as cor pulmonale. In this condition, the right side of the heart becomes enlarged, due to increased pressure inside blood vessels in the lung etc. (e.g. as a result of COPD – see above);
- if you suffer from severe bronchial asthma;
- if you have a type of bowel obstruction (paralytic ileus) not caused by opioids;
- if you have moderate to severe liver problems.

**Warnings and Precautions**

Talk to your doctor or pharmacist before taking these tablets:

- in the case of elderly or debilitated (weak) patients;
- if you have a type of bowel obstruction (paralytic ileus) caused by opioids;
• if you have kidney problems;
• if you have mild liver problems;
• if you have severe lung problems (i.e. reduced breathing capacity);
• if you have myxoedema (a thyroid disorder, with dryness, coldness and swelling [‘puffiness’] of the skin, affecting the face and limbs);
• if your thyroid gland is not producing enough hormones (underactive thyroid or hypothyroidism);
• if your adrenal glands are not producing enough hormones (adrenal insufficiency or Addison’s disease);
• if you have a mental disorder as a result of an intoxication (toxic psychosis);
• if you suffer from gallstone problems;
• if your prostate gland is abnormally enlarged (prostate hypertrophy);
• if you are addicted to alcohol or drugs, or have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping alcohol or drugs;
• if your pancreas is inflamed (pancreatitis);
• if you have low blood pressure (hypotension);
• if you have high blood pressure (hypertension);
• if you have heart problems;
• if you have a head injury (due to the risk of increased brain pressure);
• if you suffer from epilepsy or are prone to fits;
• if you are also taking a type of medicine known as a MAO inhibitor (used to treat depression or Parkinson’s disease) e.g. medicines containing tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid.

These tablets are not recommended for use in patients with advanced digestive or pelvic cancers where bowel obstruction may be a problem.

Children and adolescents
These tablets must not be given to children or adolescents under 18 years of age as the safety and benefits have not been shown yet.

How to use Targin tablets correctly
If you experience severe diarrhoea at the start of treatment (within the first 3-5 days) this may be due to the effect of naloxone. It may be a sign that your bowel movements are returning to normal. If diarrhoea persists after 3-5 days, or it gives you cause for concern, please contact your doctor.

If you have been using high doses of another opioid, withdrawal symptoms (such as restlessness, bouts of sweating or muscle pain) may occur when you initially switch to taking these tablets. If you experience withdrawal symptoms, you may need to be specially monitored by your doctor.

If you need to undergo surgery, please tell your doctor that you are taking these tablets.

If you have been taking these tablets for a long time, you may become tolerant. This means you may need a higher dose to achieve the desired pain relief. Long-term use of these tablets may also lead to addiction. Withdrawal symptoms may occur if treatment is stopped too suddenly. If you no longer need treatment, you should reduce your daily dose gradually, in consultation with your doctor.

As with other strong opioid painkillers, there is a risk that you may develop a psychological dependence to oxycodone.

You may notice remains of the tablet in your stools. Do not be alarmed, as the active ingredients will have already been released in the stomach and gut, and absorbed into your body.

Incorrect use of Targin tablets
You must swallow these tablets whole so as not to affect the slow release of oxycodone. Do not break, chew or crush these tablets. Taking broken, chewed or crushed tablets may result in your body absorbing a potentially fatal dose of oxycodone (see under ‘If you take more Targin tablets than you should’).

These tablets are not suitable for withdrawal treatment.
These tablets should never be abused, particularly if you have a drug addiction. If you are addicted to drugs such as heroin, morphine or methadone, severe withdrawal symptoms are likely if you abuse these tablets because they contain the ingredient naloxone. Pre-existing withdrawal symptoms may be made worse.

You should never misuse the tablets by dissolving and injecting them (e.g. into a blood vessel). They contain talc, which can cause destruction of local tissue (necrosis) and changes in lung tissue (lung granuloma). Misuse can also have other serious consequences which may be fatal.

The use of these tablets may produce positive results in drugs tests.

Other medicines and Targin tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. The risk of side effects is increased if you take these tablets at the same time as medicines which affect the way the brain works. For example, you may feel very sleepy, or breathing problems may get worse.

Examples of medicines that affect the way the brain works include:

- other strong painkillers (opioids);
- sleep medication and tranquillisers (sedatives, hypnotics);
- antidepressants;
- medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics);
- other medicines which act on the nervous system (phenothiazines, neuroleptics).

Tell your doctor if you are taking:

- medicines that decrease the blood’s clotting ability (coumarin derivatives), this clotting time may be speeded up or slowed down;
- antibiotics of the macrolide type (such as clarithromycin);
- antifungal medicines of the –azole type (e.g. ketoconazole);
- ritonavir or other protease inhibitors (used to treat HIV);
- rifampicin (used to treat tuberculosis);
- carbamazepine (used to treat seizures, fits or convulsions and certain pain conditions);
- phenytoin (used to treat seizures, fits or convulsions).

Targin tablets with food, drink and alcohol

Drinking alcohol whilst taking these tablets may make you feel more sleepy or increase the risk of serious side effects such as shallow breathing with a risk of stopping breathing, and loss of consciousness. It is recommended not to drink alcohol while you’re taking these tablets.

You should avoid drinking grapefruit juice while you are taking these tablets.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Use of these tablets during pregnancy should be avoided unless your doctor thinks treatment with this medicine is essential. If used over prolonged periods during pregnancy, oxycodone may lead to
withdrawal symptoms in the newborn baby. If oxycodone is given during childbirth, the baby may have breathing problems (respiratory depression).

**Breastfeeding**
Breastfeeding should be discontinued during treatment with these tablets. Oxycodone passes into breast milk. It is not known whether naloxone also passes into breast milk.

**Driving and using machines**
These tablets may affect your ability to drive or operate machines. This is most likely at the start of your treatment, after a dose increase or after switching from a different medication. These side effects should disappear once you are on a stable dose.
Ask your doctor whether you may drive or operate machines.

*Targin tablets contain lactose*
These tablets contain lactose (milk sugar). If you have been told that you have an intolerance to some sugars, contact your doctor before taking these tablets.

3. **How to take Targin tablets**
Always take these tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

**Adults**
The usual starting dose is 10 mg oxycodone hydrochloride / 5 mg naloxone hydrochloride every 12 hours.
Your doctor will decide how much you should take every day and how to divide your total daily dose into morning and evening doses. They will also decide on any necessary dose adjustments during treatment depending on your level of pain and individual sensitivity. You should be given the lowest dose needed for pain relief. If you have already been treated with opioids, your treatment with these tablets may be started at a higher dose.
The maximum daily dose is 80 mg oxycodone hydrochloride and 40 mg naloxone hydrochloride. If you need a higher dose, your doctor may give you additional oxycodone without naloxone. However, the maximum daily dose of oxycodone should not exceed 400 mg. The beneficial effect of naloxone on bowel movements may be affected if additional oxycodone is given without additional naloxone.
If you change from these tablets to another strong painkiller your bowel problems may get worse.
If you experience pain between doses, you may need to take an additional fast-acting painkiller. These tablets are not suitable for this. Please talk to your doctor.
If you feel that these tablets are too strong or too weak, please talk to your doctor or pharmacist.

**Elderly patients**
In general, no dose adjustment is necessary for elderly patients with normal kidney and/or liver function.

**Liver or kidney problems**
If you have kidney or mild liver problems your doctor may prescribe a lower dose. You must not take these tablets if you have moderate or severe liver problems, (see also Section 2 “Do not take Targin tablets” and “Warnings and precautions”).

**Children and adolescents below 18 years of age**
No studies have been carried out to show that these tablets work properly in children and adolescents, or are safe for them to take. They are therefore not recommended for use in patients under 18 years of age.

**Method of administration**
Swallow your tablets whole with a glass of water. You can take these tablets with or without food. Take them every 12 hours. For instance, if you take a tablet at 8 o’clock in the morning, you should take your next tablet at 8 o’clock in the evening. Do not break, chew or crush the tablets.

**Duration of use**
You should not take these tablets for any longer than you need to. If you have been taking them for a long time your doctor should regularly check that you still need them.

**If you take more Targin tablets than you should**
If you have taken more than the prescribed dose, you must inform your doctor immediately. An overdose may result in:
- a reduction in size of pupils in the eye;
- breathing more slowly or weakly than expected (respiratory depression);
- drowsiness or loss of consciousness;
- low muscle tone (hypotonia);
- reduced pulse rate;
- a fall in blood pressure.

In severe cases, loss of consciousness (coma), fluid on the lungs and circulatory collapse may occur, which may be fatal.

You should avoid situations which require you to be alert, e.g. driving.

**If you forget to take Targin tablets,**
or if you take a lower dose than the one prescribed, you may not feel any painkilling effect.

If you forget to take your tablets and your next usual dose is due in 8 hours time or more: Take the forgotten dose immediately and continue with your normal dosing routine. If your next usual dose is due in less than 8 hours time: Take the forgotten dose, then, wait another 8 hours before taking your next dose. Try to get back in your normal dosing routine (e.g. 8 o’clock in the morning and 8 o’clock in the evening).

Do not take more than one dose within any 8 hour period.
Do not take a double dose to make up for a forgotten dose.

**If you stop taking Targin tablets**
Do not stop taking these tablets without first speaking with your doctor. If you do not require any further treatment, your doctor will advise you how to reduce the daily dose gradually. In this way, you will avoid withdrawal symptoms, such as restlessness, bouts of sweating and muscle pain.

If you have any further questions on the use of these tablets, ask your doctor or pharmacist.

### 4. Possible side effects

**Like all medicines, these tablets can cause side effects, although not everybody gets them.**

**Important side effects or signs to look out for, and what to do if you are affected:**

If you are affected by any of the following important side effects, consult a doctor immediately. The most serious side effect is a condition where you breathe more slowly or weakly than expected (respiratory depression). It mostly occurs in elderly and weak patients. Opioids can also cause a severe drop in blood pressure in susceptible patients.

**Common (may affect up to 1 in 10 people)**
- abdominal pain
- constipation
- diarrhoea
- dry mouth
- indigestion
- vomit (be sick)
- feel sick
- wind
- decreased appetite up to loss of appetite
- a feeling of dizziness or ‘spinning’
- headache
- hot flushes
- general weakness
- itchy skin
- skin reactions/rash
- sweating
- vertigo
- difficulty in sleeping
- drowsiness

Uncommon (may affect up to 1 in 100 people)
- abdominal bloating
- abnormal thoughts
- anxiety
- confusion
- depression
- nervousness
- chest tightness especially if you already have coronary heart disease
- drop in blood pressure
- withdrawal symptoms such as agitation
- fainting
- palpitations
- biliary colic
- chest pain
- generally feeling unwell
- pain
- swelling of the hands, ankles or feet
- weight loss
- difficulties to concentrate
- impaired speaking
- shaking
- difficulties breathing
- restlessness
- chills
- hepatic enzymes increased
- rise in blood pressure
- runny nose
- cough
- hypersensitivity/allergic reactions
- injuries from accidents
- increased urge to urinate
- muscle cramps
- muscle twitches
- muscle pain
- vision impairment
- epileptic seizures (especially in people with epileptic disorder or a predisposition to seizures)

Rare (may affect up to 1 in 1,000 people)
- increase in pulse rate
- dental changes
- yawning
- weight gain

Not known (frequency cannot be estimated from the available data)
- euphoric mood
- severe drowsiness
- erectile dysfunction
- nightmares
- hallucinations
- shallow breathing
- difficulties in passing urine
- tingling in the hands or feet
- belching

The active ingredient oxycodone hydrochloride, if not combined with naloxone hydrochloride, is known to have the following differing side effects:

Breathing problems, such as breathing more slowly or weakly than expected (respiratory depression), reduction in size of the pupils in the eye, muscle cramps and decreased cough reflex.

**Common** (may affect up to 1 in 10 people)
- altered mood and personality changes (e.g. depression, a feeling of extreme happiness)
- decreased activity
- increased activity
- difficulties in passing urine
- hiccups

**Uncommon** (may affect up to 1 in 100 people)
- impaired concentration
- migraines
- taste anomalies
- increased muscle tension
- involuntary muscle contractions
- drug dependence
- ileus
- dry skin
- drug tolerance
- reduced sensitivity to pain or touch
- abnormal coordination
- vocal changes (dysphonia)
- water retention
- difficulties in hearing
- mouth ulcers
- difficulties in swallowing
- sore gums
- perception disturbances (e.g. hallucinations, derealisation)
- reduced sexual drive
- flushing of the skin
- dehydration
- agitation
- thirst

**Rare** (may affect up to 1 in 1,000 people)
- itching rash (urticaria)
- herpes simplex
- increased appetite
- dark (tarry) stools
- gingival bleeding
Not known (frequency cannot be estimated from the available data)
- acute generalized allergic reactions (anaphylactic reactions)
- absence of menstrual periods
- problems with bile flow

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971;
Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Targin tablets
Keep out of the sight and reach of children.

Do not use any tablets after the expiry date which is stated on the carton and blister, after ‘EXP…’ The expiry date refers to the last day of the month.

Do not store above 25°C.
Store in the original package in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Targin tablets contain

The active ingredients are oxycodone hydrochloride and naloxone hydrochloride.

Each 5 mg/2.5 mg tablet contains 5 mg of oxycodone hydrochloride (equivalent to 4.5 mg oxycodone), and 2.73 mg naloxone hydrochloride dihydrate (equivalent to 2.5 mg naloxone hydrochloride and 2.25 mg naloxone).

Each 10 mg/5 mg tablet contains 10 mg of oxycodone hydrochloride (equivalent to 9 mg oxycodone), and 5.45 mg naloxone hydrochloride dihydrate (equivalent to 5 mg naloxone hydrochloride and 4.5 mg naloxone).

Each 20 mg/10 mg tablet contains 20 mg of oxycodone hydrochloride (equivalent to 18 mg oxycodone) and 10.9 mg naloxone hydrochloride dihydrate (equivalent to 10 mg naloxone hydrochloride and 9 mg naloxone).

Each 40 mg/20 mg tablet contains 40 mg of oxycodone hydrochloride (equivalent to 36 mg oxycodone) and 21.8 mg naloxone hydrochloride dihydrate (equivalent to 20 mg of naloxone hydrochloride and 18 mg naloxone).

The other ingredients are:

Tablet core:
hydroxypropylcellulose (5 mg/2.5 mg strength tablet only), povidone K30 (10 mg/5 mg, 20 mg/10 mg and 40 mg/20 mg strength tablets only), ethyl cellulose, stearyl alcohol, lactose monohydrate, talc, magnesium stearate

Tablet coat: polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc

The 5 mg/2.5 mg tablets also contain brilliant blue (E133), the 20 mg/10 mg tablets also contain iron (III) oxide red (E172) and the 40 mg/20 mg tablets contain iron oxide yellow (E172).

**What Targin tablets look like and the contents of the pack**

**Targin** 5 mg/2.5 mg tablets are blue, oblong, film coated tablets, marked ‘OXN’ on one side and ‘5’ on the other.

**Targin** 10 mg/5 mg tablets are white, oblong, film coated tablets, marked ‘OXN’ on one side and ‘10’ on the other.

**Targin** 20 mg/10 mg tablets are pink, oblong, film coated tablets, marked ‘OXN’ on one side and ‘20’ on the other.

**Targin** 40 mg/20 mg tablets are yellow, oblong, film coated tablets, marked ‘OXN’ on one side and ‘40’ on the other.

In each box there are 56 tablets.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder:**

Mundipharma Pharmaceuticals Limited  
Millbank House,  
Arkle Road,  
Sandyford,  
Dublin 18,  
Ireland.

**Manufacturers:**

Mundipharma GmbH  
Mundipharma Straße 2, 65549 Limburg/Lahn, Germany

Bard Pharmaceuticals Limited  
Cambridge Science Park, Milton Road, Cambridge  
CB4 0GW, UK.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

<table>
<thead>
<tr>
<th>Country</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>Targin®</td>
</tr>
<tr>
<td>Belgium</td>
<td>Targinact®</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>Targin®</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>Targin®</td>
</tr>
<tr>
<td>Germany</td>
<td>Targin®</td>
</tr>
<tr>
<td>Denmark</td>
<td>Targin®</td>
</tr>
<tr>
<td>Estonia</td>
<td>Targinact®</td>
</tr>
</tbody>
</table>
Spain       Targin®
Finland     Targiniq®
France      Targinact®
Hungary     Targinact®
Ireland     Targin®
Iceland     Targin®
Italy       Targin®
Latvia      Targin®
Luxembourg  Targinact®
The Netherlands Targinact®
Norway      Targiniq®
Poland      Targin®
Portugal    Targin®
Romania     Targin®
Slovakia    Targin®
Slovenia    Targinact®
Sweden      Targiniq®
United Kingdom Targinact®

This leaflet is also available in large print, Braille or as an audio CD.
To request a copy, please call the RNIB Medicine Information line on:
0044 1733 37 53 70
You will need to give details of the product name and reference number.
These are as follows:
Product name: Targin
Reference number: 1668/10/2

This leaflet was last revised in January 2015

© TARGIN, MUNDIPHARMA and the ‘mundipharma’ device (logo) are Registered Trade Marks.