PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S6

TarginAct® 5 mg/2,5 mg Prolonged-Release Tablets

TarginAct® 10 mg/5 mg Prolonged-Release Tablets

TarginAct® 20 mg/10 mg Prolonged-Release Tablets

TarginAct® 40 mg/20 mg Prolonged-Release Tablets

Active substances

Oxycodone hydrochloride and naloxone hydrochloride

Sugar / sweetener status

Contains sugar (Lactose monohydrate).

Read all of this leaflet carefully before you start taking TarginAct®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- TarginAct® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TarginAct® is and what it is used for
2. What you need to know before you take TarginAct®
3. How to take TarginAct®

4. Possible side effects

5. How to store TarginAct®

6. Contents of the pack and other information

1. What TarginAct® is and what it is used for

TarginAct® is a strong analgesic (medicines used to treat pain) and belongs to a group of medicines called opioids.

These tablets are only for use in adults.

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

TarginAct® is indicated for the treatment of moderate to severe pain, which requires the use of an opioid analgesic (medicine used to treat pain).

TarginAct® is indicated as a second line symptomatic treatment of idiopathic Restless Legs Syndrome (RLS) in people who cannot be treated with dopamine medicines. RLS is a condition that causes an uncontrollable urge to move your legs, usually as a result of an unpleasant sensation in your limbs. This can start as soon as you sit or lie down and is only relieved by an irresistible urge to move the legs, sometimes the arms and other parts of the body. It makes sitting still and sleeping very difficult.

The naloxone component of TarginAct® reduces the potential for constipation caused by oxycodone hydrochloride.

2. What you need to know before you take TarginAct®

Do not take TarginAct®:

- if you are hypersensitive (allergic) to oxycodone or naloxone, or any of the other ingredients of TarginAct® (refer to section 6);
- in any situation where opioids (a class of medicines used to treat pain) are

contraindicated;

- 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 (a condition whereby the right side of the heart becomes enlarged, due to increased blood pressure in the lungs);
- if you suffer from severe bronchial asthma;
- if you have a type of bowel (lower intestine) obstruction called paralytic ileus, which is not caused by opioid class (strong pain medication) medicines;
- if you have moderate to severe liver problems;
- if you have moderate to severe kidney problems;
- if you have a condition called sleep apnoea (a sleep disorder in which your breathing repeatedly stops and starts);
- if you have a history of opioid abuse.

Warnings and precautions

Take special care with TarginAct®:

- if you are elderly or debilitated (weak);
- if you have a type of bowel (lower intestine) obstruction called paralytic ileus, which is caused by opioid class (strong pain medication) medicines;
- if you have mild kidney problems;
- if you have mild liver problems;
- if you have severe lung problems (breathing difficulty);
- if you have a condition called myxoedema (a thyroid disorder which may occur when your thyroid gland is not producing enough hormones, which results in swelling of the skin (puffiness), 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 called toxic psychosis, which may be caused by intoxication or drugs;
- if you suffer from gallstone problems;
- if your prostate gland is abnormally enlarged (prostate hypertrophy);
- if you are addicted to alcohol or have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping the use of 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 pressure in the brain);
- if you suffer from epilepsy or are prone to fits (convulsions);
- if you are also taking a type of medicine known as a monoamine oxidase inhibitor (MAOI) (used to treat depression or Parkinson's disease), which includes medicines containing tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid;
- if you have been receiving long-term opioid treatment with higher doses of opioids and are switched to TarginAct® as you may suffer from withdrawal symptoms;
- if you have been receiving long-term treatment with TarginAct®, as you may develop a tolerance to the prescribed dose, which may require higher doses to be prescribed to provide the desired pain relief;
- if you have been receiving long-term treatment with TarginAct®, as this may lead to physical or psychological dependence (addiction) on the product;

- if you have been receiving long-term treatment with TarginAct®, and stop taking it immediately, as you may suffer from withdrawal symptoms;
- if you are a professional athlete, as TarginAct® may produce positive results in doping controls;
- if you are about to have an operation or for the first 12-24 hours after an operation;
- if you have any problems with your biliary tract or bile ducts.

You may have a greater risk of becoming dependent or addicted on TarginAct® if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs (“addiction”).
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If any of these warning signs apply to you, talk to your doctor before starting to take these tablets.

Tolerance, dependence and addiction

This medicine contains oxycodone which is an opioid medicine. Repeated use of opioid painkillers can result in the medicine being less effective (you become accustomed to it, known as tolerance). Repeated use of TarginAct® can also lead to dependence, abuse, and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it. You might feel that you need to carry on taking your medicine, even when it doesn’t help to relieve your pain or severe Restless Legs Syndrome.

The risk of becoming dependent or addicted varies from person to person.

If you notice any of the following signs whilst taking TarginAct®, it could be a sign that you have become dependent or addicted:

- You need to take the medicine for longer than advised by your doctor;
- You need to take more than the recommended dose;
- You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep';
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine;
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects').

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, 'If you stop taking TarginAct®').

Sleep-related breathing disorders

TarginAct® can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxaemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms in you, contact your doctor. A dose reduction may be considered by your doctor.

Opioid-induced hyperalgesia (OIH) and allodynia

OIH is a condition that can occur at any dosage of an opioid, but it may occur more often with higher doses and longer-term use. Talk to your health care provider if your pain increases (hyperalgesia), if you feel more sensitive to pain (allodynia), or if you have new pain after taking your opioid pain medicine.

TarginAct® is not recommended for use in patients with advanced digestive (stomach or intestine) or pelvic cancers where bowel (lower intestine) obstruction may be a problem.

Other medicines and TarginAct®

Always tell your health care provider if you are taking any other medicine (This includes all complementary or traditional medicines).

If you take TarginAct® with other medicines, the effect of TarginAct® or the other medicines may be changed.

Medicines or substances, which have effects on the central nervous system (CNS) (CNS-depressant effects), e.g. alcohol, other opioid class medicines (strong pain medicines), medicines to help you sleep (including benzodiazepines), antidepressants (including medicine belonging to a group called MAO-inhibitors (such as tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid), mood stabilising medication, antihistamines (medicines for allergies or travel sickness) and anti-emetics (medicines to stop you from vomiting) may increase the effect of TarginAct® on your breathing ability.

If you are taking TarginAct® with medicines which decrease the blood's clotting ability (warfarin), your blood clotting time may be faster or slower.

Using TarginAct® with antidepressants that increase the amount of serotonin in the brain, known as Selective Serotonin Re-uptake Inhibitor (SSRI) or a Serotonin Norepinephrine Re-uptake Inhibitor (SNRI) may cause serotonin toxicity. Symptoms can include agitation, hallucinations, faster heartbeat, sudden changes in blood pressure, high body temperature, over-active reflexes, incoordination, muscle stiffness, nausea, vomiting, or diarrhoea.

If you are taking TarginAct® with medicines known as anticholinergics or medications with anticholinergic activity (examples include tricyclic antidepressants, antihistamines, antipsychotics, muscle relaxants, anti-Parkinson medicines), it may increase the side effects of these medicines.

Tell your doctor or pharmacist:

- if you are taking antibiotics (such as clarithromycin)
- if you are taking antifungal medicines (such as ketoconazole)
- if you are taking medicine to treat HIV (such as ritonavir)
- if you are taking medicine to treat tuberculosis (such as rifampicin)
- if you are taking medicine to treat epilepsy (such as carbamazepine or phenytoin)
- if you are taking medicine to treat depression (such as paroxetine or St. John's wort)
- if you are taking quinidine (a medicine to treat a fast heartbeat)

Grapefruit juice may also increase the blood levels of oxycodone and should not be drunk whilst taking TarginAct®.

TarginAct® with food and drink

You can take TarginAct® with or without food.

Drinking alcohol during your treatment with TarginAct® may make you sleepy or increase the risk of serious side effects, such as shallow breathing with the risk to stopping breathing, and loss of consciousness. It is recommended not to drink alcohol while you are taking TarginAct®.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice

before taking this medicine.

TarginAct® is not recommended for use in pregnancy or during labour. Both oxycodone and naloxone pass into the placenta.

Use of these tablets during pregnancy should be avoided. 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).

TarginAct® should not be used in mothers breastfeeding their infants as oxycodone passes into breast milk. It is not known whether naloxone also passes into breast milk.

Driving and using machines

TarginAct® may reduce your ability to drive and use machines safely. This is particularly likely:

- at the beginning of your treatment with TarginAct®;
- after the dose of TarginAct® has been increased or the product has been rotated (if you previously received another type of opioid medicine class and have been switched to TarginAct®); and
- if TarginAct® is combined with alcohol or other central nervous system (CNS) depressant agents (e.g. medicines to help you sleep, antidepressants, mood stabilising medication, antihistamines (medicines for allergies or travel sickness) and anti-emetics (medicines to stop you from vomiting).

Consult your doctor whether you are permitted to drive or use machinery.

TarginAct® contains:

Tablet core: ethylcellulose, lactose monohydrate, magnesium stearate, stearyl alcohol, talc.

TarginAct® 5 mg/2,5 mg contains hydroxypropylcellulose.

TarginAct® 10 mg/5 mg; 20 mg/10 mg and 40 mg/20 mg contain povidone K30.

Tablet coat: polyvinylalcohol, macrogol, talc, titanium dioxide.

TarginAct® 5 mg/2,5 mg contains Brilliant blue FCF aluminium lake.

TarginAct® 10 mg/5 mg contains no additional colourant.

TarginAct® 20 mg/10 mg contains Iron oxide red.

TarginAct® 40 mg/20 mg contains Iron oxide yellow.

TarginAct® contains lactose (milk sugar). If you have lactose intolerance, galactose intolerance, or glucose-galactose malabsorption or intolerance to any other sugars, contact your doctor or health care provider before taking TarginAct®.

3. How to take TarginAct®

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are unsure. Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using TarginAct®, when and how long you need to take it, when to contact your doctor, and when you need to stop taking it (see also if you stop taking TarginAct®).

Do not share medicines prescribed for you with any other person.

TarginAct® must be taken orally and should be swallowed whole, without being broken or chewed. It is normal to find the shell of the tablet in your stool, this does not mean that the tablet has not dissolved and is not working.

Your doctor will determine the correct dose for you to treat your pain or Restless Legs Syndrome. Your doctor will advise you at what times you should take your dose in the mornings and evenings.

You should not exceed the dose recommended by your doctor.

If you are being treated for Restless Legs Syndrome, your doctor should be experienced in the management of Restless Legs Syndrome.

Pain

Adults

The usual starting dose is one TarginAct® 10 mg/5 mg tablet every 12 hours.

Your doctor may adjust your dose during treatment, depending on your level of pain and how you respond to TarginAct®.

The maximum daily dose is 80 mg oxycodone hydrochloride and 40 mg naloxone hydrochloride (e.g. one TarginAct® 40 mg/20 mg tablet twice a day).

If you experience pain between doses, talk to your doctor, who may need to increase your TarginAct® dose.

Restless Legs Syndrome

Adults

The usual starting dose is one TarginAct® 5 mg/2,5 mg tablet every 12 hours.

Your doctor may adjust your dose and when you should take it during treatment, depending on how your Restless Legs Syndrome responds to TarginAct®.

The maximum daily dose is 60 mg oxycodone hydrochloride and 30 mg naloxone hydrochloride (e.g. one TarginAct® 20 mg/10 mg tablet and one TarginAct® 10 mg/5 mg tablet twice a day or three TarginAct® 10 mg/5 mg tablets twice a day).

Children and adolescents under 18 years

The safety and efficacy of TarginAct® in patients below the age of 18 years have not been established and TarginAct® is not recommended for use in this patient group.

Elderly patients

The dosing of elderly patients is the same as that for younger adults.

Impaired kidney or liver function

If you have mild kidney or liver function problems, your doctor may prescribe a lower dose.

If you have moderate to severe impairment of liver or kidney function, these tablets should not be used.

Your doctor will tell you how long your treatment with TarginAct® will last.

When you no longer require TarginAct® treatment, your doctor may reduce your dose over time.

If you think that the effect of TarginAct® is too strong or weak, tell your doctor or pharmacist.

If you take more TarginAct® than you should

In the event of overdose, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre. An overdose may result in a brain disorder (known as toxic leukoencephalopathy).

If you forget to take TarginAct®

Do not take a double dose to make up for forgotten individual doses.

If you forget to take your tablets and your next usual dose is due in 8 hours' time or more:

Take the forgotten tablet immediately and continue with your normal dosing routine.

Do not take more than one dose of TarginAct® within any 8-hour period.

If you stop taking TarginAct®

Do not stop taking TarginAct® without first speaking with your doctor. If you do not require any further treatment with TarginAct®, your doctor will advise you how to reduce the daily dose gradually.

You may become constipated when you discontinue use of TarginAct® or switch to another painkiller. Your doctor can prescribe something to assist with this.

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

4. Possible side effects

TarginAct® can have side effects.

Not all side effects reported for TarginAct® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TarginAct®, please consult your health care provider for advice.

If any of the following happens, stop taking TarginAct® and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting;
- yellowing of the skin and eyes, also called jaundice.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TarginAct®. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital, if you notice any of the following:

Frequent side effects

- loss of appetite
- finding it difficult to balance when standing up (vertigo)
- hot flushes
- decreased blood pressure
- restlessness
- being unable to sleep (insomnia)
- drowsiness (feeling sleepy)
- abdominal (stomach) pain
- constipation
- diarrhoea
- nausea and vomiting
- increased liver enzymes (observed after taking a liver test)
- itchy skin
- rash
- sweating
- medicine withdrawal symptoms such as agitation, anxiety, shaking or sweating
- feeling hot and cold
- chills
- lack of energy (asthenia)
- tiredness or exhaustion

Less frequent side effects

- hypersensitivity (allergy)
- visual impairment (having sight problems)
- chest pain (angina pectoris), particularly in patients with a history of heart disease
- increased heartbeat (tachycardia) or irregular heartbeat (palpitations)

- increased blood pressure
- mood changes, including the way that you think, feeling anxious, feeling depressed, feeling very happy or feeling confused
- hallucinating (seeing things that do not exist)
- feeling nervous
- decreased sexual drive
- having nightmares
- medicine dependence
- having difficulty to concentrate
- having a tingling sensation on your hands, arms, legs, feet or skin (paraesthesia)
- changes in ability to taste
- speech disorder
- uncontrollable shaking (tremor)
- epileptic fits (convulsions)
- feeling more relaxed, calm or sleepy than usual (sedation)
- breathing repeatedly stops and starts during sleep (you may snore loudly and / or feel tired even after a full night's sleep)
- feeling a lack of energy and sluggishness (lethargy)
- fainting
- swelling of the stomach (abdominal distension)
- dental changes
- abdominal pain related to the gallbladder due to gallstones
- difficulty or being unable to pass urine
- muscle pains, cramps or twitches
- a sudden urge to pass urine
- shortness of breath and breathing difficulty
- chest pain

- feeling weak and unwell (malaise)
- pain
- swelling of the hands and feet (peripheral oedema)
- weight loss or increase
- thirst
- injuries from accidents
- aggression

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- dizziness
- headaches
- dry mouth
- heartburn (indigestion)
- flatulence (feeling full of wind)

Less frequent side effects

- breaking wind (burping)
- erectile dysfunction
- running nose
- cough
- yawning

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

Frequent side effects

- change in mood and personality
- decreased or increased activity
- agitation
- hiccups
- difficulty in passing urine

Less frequent side effects

- herpes virus infections, which may cause blisters around the mouth or genitals
- serious allergic reactions
- dehydration
- increased appetite
- perception disturbances (e.g. hallucinations, feeling removed from reality)
- decreased sexual drive
- having difficulty to concentrate
- migraines
- changes in ability to taste
- increased muscle tension resulting in stiff arms or legs (hypertonia)
- uncontrollable muscle contractions
- reduced sensitivity to touch or sensation
- coordination problems
- excessive contraction of the pupil of the eye (miosis)
- hearing difficulty
- widening of blood vessels (vasodilation), which can cause low blood pressure
- voice alteration (dysphonia)
- mouth ulcers and inflammation of the mouth
- dark coloured tarry stools

- bleeding of the gums
- difficulty to swallow
- a condition where the small bowel (part of your lower intestine) does not work properly (ileus)
- swelling or inflammation of the pancreas (pancreatitis)
- dry skin
- skin rash, which is usually red and has raised itchy bumps
- absence of menstrual periods
- decrease in sex hormone production (hypogonadism)
- water retention
- thirst
- a need to take increasingly higher doses of TarginAct® to gain the same level of pain relief (tolerance)

Side effects of which the frequency is unknown

- increased sensitivity to pain which cannot be improved by increasing the dose
- tooth decay
- problems with bile flow
- withdrawal symptoms in newborn infants

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting

platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of TarginAct®.

Alternatively report to: ZADrugSafety@mundipharma.co.za

5. How to store TarginAct®

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store this medicine in a locked safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.
- Store at or below 25 °C.
- Do not remove from the outer carton until required for use.
- Do not use any tablets after the expiry date which is stated on the carton and blister.
- Do not use TarginAct® if you notice any discolouration of the tablets.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TarginAct® contains

The active substances are oxycodone hydrochloride and naloxone hydrochloride.

Each TarginAct® 5 mg/2,5 mg contains 5 mg oxycodone hydrochloride and 2,5 mg naloxone hydrochloride. Contains lactose 71,75 mg.

Each TarginAct® 10 mg/5 mg contains 10 mg oxycodone hydrochloride and 5,0 mg naloxone hydrochloride. Contains lactose 64,25 mg.

Each TarginAct® 20 mg/10 mg contains 20 mg oxycodone hydrochloride and 10,0 mg naloxone hydrochloride. Contains lactose 54,50 mg.

Each TarginAct® 40 mg/20 mg contains 40 mg oxycodone hydrochloride and 20,0 mg naloxone hydrochloride. Contains lactose 109 mg.

The other ingredients are:

Tablet core: ethylcellulose, lactose monohydrate, magnesium stearate, stearyl alcohol, talc.

TarginAct® 5 mg/2,5 mg contains hydroxypropylcellulose.

TarginAct® 10 mg/5 mg; 20 mg/10 mg and 40 mg/20 mg contain povidone K30.

Contains sugar. This product contains lactose monohydrate.

Tablet coat: polyvinylalcohol, macrogol, talc, titanium dioxide.

TarginAct® 5 mg/2,5 mg contains Brilliant blue FCF aluminium lake.

TarginAct® 10 mg/5 mg contains no additional colourant.

TarginAct® 20 mg/10 mg contains Iron oxide red.

TarginAct® 40 mg/20 mg contains Iron oxide yellow.

What TarginAct® looks like and contents of the pack

TarginAct® 5 mg/2,5 mg is a blue capsule shaped tablet, marked “OXN” on one side and “5” on the other side.

TarginAct® 10 mg/5 mg is a white capsule shaped tablet, marked “OXN” on one side and “10” on the other side.

TarginAct® 20 mg/10 mg is a pink capsule shaped tablet, marked “OXN” on one side and “20” on the other side.

TarginAct® 40 mg/20 mg is a yellow capsule shaped tablet, marked “OXN” on one side and “40” on the other side.

TarginAct® is supplied in clear PVC and silver aluminium foil blister packs of 28, which are

enclosed in a cardboard carton.

Holder of Certificate of Registration

Mundipharma (Pty) Ltd

Block D, Grosvenor Square,

Park Lane, Century City,

7441, Cape Town,

South Africa

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Registration numbers

South Africa: S6

TarginAct® 5 mg/2,5 mg:	46/2.9/0645
TarginAct® 10 mg/5 mg:	46/2.9/0646
TarginAct® 20 mg/10 mg:	46/2.9/0647
TarginAct® 40 mg/20 mg:	46/2.9/0648

Namibia: NS4

TarginAct® 5 mg/2,5 mg:	16/2.9/0137
TarginAct® 10 mg/5 mg:	16/2.9/0138
TarginAct® 20 mg/10 mg:	16/2.9/0139
TarginAct® 40 mg/20 mg:	16/2.9/0140

Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.

® = TarginAct® is a registered trademark.