PATIENT INFORMATION LEAFLET

TarginAct® Prolonged Release Tablets

SCHEDULING STATUS:

S6

PROPRIETARY NAMES, STRENGTHS AND PHARMACEUTICAL FORMS:

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

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 or your pharmacist.
- **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.

1. 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.

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 and

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

2. WHAT TarginAct® IS USED FOR

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

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 severe pain, which requires the use of a strong opioid analgesic (medicine used to treat pain) and to reduce the risk of constipation.

3. 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®**;
- 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.

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 (addiction) dependence 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 any of these warnings apply to you, talk to your doctor before starting to take these tablets.

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.

Taking 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 your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **TarginAct®**.

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).

Breastfeeding should be discontinued during treatment with **TarginAct®**. Oxycodone passes into breast milk. It is not known whether naloxone also passes into breast milk. **TarginAct®** should therefore not be used in mothers breastfeeding their infants.

Driving and using machinery:

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, anti-histamines (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.

Important information about some of the ingredients of TarginAct®:

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

Taking other medicines with TarginAct®:

Always tell your healthcare professional if you are taking any other medicine (This includes 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, antidepressants, mood stabilising medication, anti-histamines (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.

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 heart beat).

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

4. HOW TO TAKE TarginAct®

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

Always take **TarginAct®** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

TarginAct® must be taken orally and should be swallowed whole, without being broken or chewed.

Your doctor will determine the correct dose for you to treat your pain. 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.

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.

Children and adolescents under 18 years:

The safety and efficacy of **TarginAct®** in patients below the age of 18 years of age has 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.

You must not take **TarginAct®** if you have moderate to severe liver or kidney function problems.

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 overdosage, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison control centre.

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.

Effects when treatment with TarginAct® is stopped:

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.

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

5. 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 this medicine, please consult your doctor, pharmacist or other healthcare professional 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)
- 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

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)
- 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

- aggression
- 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.

6. STORING AND DISPOSING OF TarginAct®

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

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 a 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).

7. PRESENTATION OF TarginAct®

TarginAct® is supplied in clear PVC and silver aluminium foil blister packs of 28, which are enclosed in a cardboard carton.

8. IDENTIFICATION OF TarginAct®

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.

9. 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

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

Date of registration: 06 August 2015

Date of last update: 17 August 2018

® = **TarginAct** is a registered trademark.