INFORMATION FOR THE PATIENT ABOUT

OxyContin® Prolonged Release Tablets

Read all of this leaflet carefully before you start taking this medicine.

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

SCHEDULING STATUS:

S6

PROPRIETARY NAME (and Dosage Form):

OxyContin® 5 mg Prolonged Release Tablets (Tablets)

OxyContin® 10 mg Prolonged Release Tablets (Tablets)

OxyContin® 20 mg Prolonged Release Tablets (Tablets)

OxyContin® 40 mg Prolonged Release Tablets (Tablets)

OxyContin® 80 mg Prolonged Release Tablets (Tablets)

1. WHAT OxyContin® Prolonged Release Tablets CONTAINS:

Each **OxyContin® 5 mg Prolonged Release Tablet** contains 5 mg of oxycodone hydrochloride.

Each **OxyContin® 10 mg Prolonged Release Tablet** contains 10 mg of oxycodone hydrochloride.

Each **OxyContin® 20 mg Prolonged Release Tablet** contains 20 mg of oxycodone hydrochloride.

Each **OxyContin® 40 mg Prolonged Release Tablet** contains 40 mg of oxycodone hydrochloride.

Each **OxyContin® 80 mg Prolonged Release Tablet** contains 80 mg of oxycodone hydrochloride.

In addition **OxyContin® Prolonged Release Tablets** contain the following inactive ingredients in the tablet core:

Lactose monohydrate, Povidone K30, Ammonio methacrylate co-polymer, Sorbic acid, Triacetin, Stearyl alcohol, Talc and Magnesium stearate.

The tablet coating contains the following ingredients:

OxyContin® 5 mg Prolonged Release Tablet: Hypromellose (E464), Macrogol 400, Titanium Dioxide (E171), Brilliant Blue (E133).

OxyContin® 10 mg Prolonged Release Tablet: Hypromellose (E464), Hyprolose, Macrogol 400, Titanium Dioxide (E171).

OxyContin® 20 mg Prolonged Release Tablet: Hypromellose (E464), Macrogol 400, Polysorbate 80, Titanium Dioxide (E171), Iron Oxide (E172).

OxyContin® 40 mg Prolonged Release Tablet: Hypromellose (E464), Macrogol 400, Polysorbate 80, Titanium Dioxide (E171), Iron Oxide (E172).

OxyContin® 80 mg Prolonged Release Tablet: Hypromellose (E464), Hyprolose, Macrogol 400, Titanium Dioxide (E171), Iron Oxide (E172), Indigo carmine (E132).

2. WHAT OxyContin® Prolonged Release Tablets ARE USED FOR:

OxyContin® Prolonged Release Tablet is a strong analgesic or “painkiller” and belongs to the group opioids.

OxyContin® Prolonged Release Tablet is used for the relief of moderate to severe pain in patients with cancer and post-operative pain, after gastrointestinal function has returned.

OxyContin® Prolonged Release Tablet is used for the relief of severe pain requiring the use of a strong opioid analgesic.

3. BEFORE TAKING OxyContin® Prolonged Release Tablets:

Do not take OxyContin® Prolonged Release Tablets

- if you are allergic (hypersensitive) to the active ingredient oxycodone hydrochloride or any of the other ingredients;
- if you suffer from severe breathing problems with a lowered supply of oxygen to the blood (hypoxia) and/or increased carbon dioxide saturation of the blood (hypercapnia);
- if you suffer from a long-term (chronic) obstructive lung disease;
- if you have a heart problem after long-term lung disease (cor pulmonale);
- if you suffer from long-term (chronic) bronchial asthma;
- where the small bowel does not work properly (paralytic ileum);
- during pregnancy and breast-feeding;
- in the presence of severe lung-, liver- or kidney diseases;
- if you are taking a type of medicine known as a monoamine oxidase inhibitor or if you have taken this type of medicine in the last two weeks;
- in any situation where opioids are contra-indicated;
- if you suffer from a head injury that causes a severe headache or makes you feel sick;
- if you suffer from severe pain in your abdomen;
- if your stomach empties more slowly than it should (delayed gastric emptying);
- if you suffer from on-going constipation (hard, infrequent stools);
- for 6 hours before an operation or for the first 24 hours after an operation;
- if you suffer from rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

Take special care with OxyContin® Prolonged Release Tablets

- with elderly or weakened patients;
- if you have an under-active thyroid (hypothyroidism), as you may need a lower dose of **OxyContin® Prolonged Release Tablets;**
- if you have poor adrenal gland function (Addison's disease);
- if you have prostate problems;
- if you have a mental disorder as a result of an infection (toxic psychosis);
- if you are or ever have been addicted to alcohol or drugs;
- if you have previously suffered from withdrawal symptoms such as agitation, anxiety; shaking or sweating, upon stopping taking alcohol or drugs;
- if you have inflammation of the pancreas (pancreatitis) or problems with your gall bladder;
- if you have a severe headache or feel sick as this may indicate that the pressure in your skull is increased;
- if you have low blood pressure (hypotension) or low blood volume (hypovolemia),
- if you have inflammatory bowel disease.

If this information applies to you or formerly applied to you, please speak to your doctor.

Use OxyContin® Prolonged Release Tablets with special caution in cases if you are or ever have been addicted to alcohol or drugs.

OxyContin® 80 mg Prolonged Release Tablets

OxyContin® 80 mg Prolonged Release Tablets should not be taken by patients, who have not taken opioids before, as their potency may lead to a life-threatening respiratory depression in this group of patients.

Children and Adolescents under 18 years of age

OxyContin® Prolonged Release Tablets has not been tested in children and adolescents under 18 years of age. Therefore safety and efficacy are not established and **OxyContin® Prolonged Release Tablets** is not recommended in children and adolescents under 18 years of age.

Elderly persons

In elderly patients without liver and/or kidney disease, a dose adjustment is usually unnecessary.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you take **OxyContin® Prolonged Release Tablets** with some other medicines, the effect of **OxyContin® Prolonged Release Tablets** or the other medicine may be changed.

OxyContin® Prolonged Release Tablets must not be used together with a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or if you have taken this type of medicine in the last two weeks.

Tell your doctor or pharmacist:

- if you are taking medicines to help you sleep (for example tranquillisers, hypnotics or sedatives);
- if you have recently been given an anaesthetic;
- if you are taking medicines to treat depression;
- if you are taking medicines to treat psychiatric or mental disorders;

- if you are taking other strong analgesics or 'painkillers';
- if you are taking muscle relaxants;
- if you are taking medicines to treat high blood pressure;
- if you are taking quinidine (a medicine to treat a fast heart beat);
- if you are taking cimetidine (a medicine for stomach ulcers, indigestion or heartburn);
- if you are taking antifungal medicines (such as ketoconazole);
- if you are taking antibiotics (such as erythromycin).

Taking OxyContin® Prolonged Release Tablets with food and drink

You can take **OxyContin® Prolonged Release Tablets** with or without food.

Drinking alcohol during your treatment with **OxyContin® Prolonged Release Tablets** may make you sleepy. If you are affected you should avoid drinking alcohol.

Pregnancy and breast-feeding

Do not take **OxyContin® Prolonged Release Tablets** during pregnancy.

The active ingredient oxycodone is transported through the placenta to the organism of the child. The long-term use of **OxyContin® Prolonged Release Tablets** during pregnancy may lead to withdrawal symptoms in newborn infants. If taken during birth, breathing problems may occur in the child.

Do not take **OxyContin® Prolonged Release Tablets** during periods of breast-feeding, since the active substance oxycodone may pass into the breastmilk.

Ask your doctor or pharmacist for advice before taking/using any medicine.

Driving and using machines

You may feel sleepy when you first start taking OxyContin® Prolonged Release Tablets, or when changing to a higher dose. If you are affected you should not drive or use machinery.

Important information about some of the ingredients of OxyContin® Prolonged Release Tablets

OxyContin® Prolonged Release Tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **OxyContin® Prolonged Release Tablets**.

4. HOW TO TAKE OxyContin® Prolonged Release Tablets

Always take **OxyContin® Prolonged Release Tablets** exactly as your doctor has told you. Do not exceed the dose recommended by your doctor. You should check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by your doctor, the usual dose for adults older than 18 years old is one prolonged release tablet of **OxyContin® 10 mg Prolonged Release Tablets** (10 mg oxycodone hydrochloride) at 12 hour intervals. Some patients may benefit from a starting dose of 5 mg to minimise the side-effects.

However, your doctor will prescribe the dose required to treat your pain. If you find that you are still in pain, or the effect too strong whilst taking **OxyContin® Prolonged Release Tablets**, discuss this with your doctor.

Swallow the prolonged-release tablets whole in order not to weaken the release of the active ingredient over an extended period of time (prolonged-release).

Some patients receiving **OxyContin® Prolonged Release Tablets** on a fixed time schedule require immediate-release painkillers for fast relief from breakthrough pain. **OxyContin® Prolonged Release Tablets** are not intended for the treatment of breakthrough pain.

Elderly persons

In elderly patients without kidney and/or liver disease, dosage adjustment is usually not necessary.

High-risk patients

Patients with kidney and/or liver disease who have not received opioids before should initially take half of the recommended adult dose. This also applies to patients with low body weight and patients who metabolise medications at slower rates.

Method of administration and duration of use

Swallow the prolonged-release tablets without chewing and with sufficient liquid (half a glass of water) in the morning and evening in accordance to a fixed time schedule (e.g. in the morning at 8 a.m., in the evening at 8 p.m.). You can take **OxyContin® Prolonged Release Tablets** with or without food.

In order to avoid weakening the prolonged release effect of the tablets, the prolonged release tablets must be swallowed whole and are not allowed to be broken, chewed or crushed. Taking broken, chewed or crushed tablets leads to speedier release of the active ingredient and to the absorption of a potentially fatal dose of the active ingredient oxycodone (see under “If you take more **OxyContin® Prolonged Release Tablets** than you should”).

OxyContin® Prolonged Release Tablets are for oral use only (swallowing of whole tablets). Improper injection (injection into a blood vessel) of the dissolved tablets must not be done, because this may lead to serious side-effects which may be fatal.

You may see residue of the tablet in your stool. Do not worry, as the active ingredient oxycodone has been released earlier while the tablet passed through the gastric system and have started to be effective in your body.

If you take more OxyContin® Prolonged Release Tablets than you should or if someone accidentally swallows your tablets

Call your doctor or hospital straight away. People who have taken an overdose may feel very sleepy and sick. They may also have breathing difficulties leading to unconsciousness or even death and may need emergency treatment in hospital. When seeking medical attention make sure that you take this leaflet and any remaining tablets with you to show to the doctor.

If you forget to take OxyContin® Prolonged Release Tablets

If you take a smaller dose of **OxyContin® Prolonged Release Tablets** than prescribed, or if you have completely forgotten to take your dose, this will lead to unsatisfactory and/or insufficient pain relief.

If you have forgotten to take your dose once, you may take it later only if the next regular dose was scheduled more than 8 hours later. You may then continue to follow your usual schedule.

If the time to the next dose is shorter, take the prolonged-release tablets, but postpone the next dose by 8 hours.

As a matter of principle, you should never take **OxyContin® Prolonged Release Tablets** more frequently than at 8-hourly intervals.

Never take a doubled amount of a single dose.

If you stop taking OxyContin® Prolonged Release Tablets

Do not stop taking **OxyContin® Prolonged Release Tablets** without telling your doctor.

If you want to stop taking your tablets, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so you do not experience unpleasant effects.

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

5. POSSIBLE SIDE EFFECTS

Like all medicines, **OxyContin® Prolonged Release Tablets** can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are rare. Tell your doctor immediately if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body.

The most serious side effect is a condition where you breathe more slowly or weakly than expected (respiratory depression).

As with all strong painkillers, there is a risk that you may become addicted or reliant on **OxyContin® Prolonged Release Tablets**.

Common side effects

(Probably affecting more than 1 in 100 people taking **OxyContin® Prolonged Release Tablets**.)

Most people will have constipation when they take **OxyContin® Prolonged Release Tablets**. Your doctor can prescribe a laxative to overcome this problem.

You may feel sick or vomit (be sick) when you take these prolonged release tablets, this should normally wear off after a few days however your doctor can prescribe an anti-vomiting medicine if it continues to be a problem.

You may find that you feel more sleepy than normal when you start taking your tablets or when your dose is increased. This should wear off after a few days.

The following side effects have also been commonly reported in patients treated with **OxyContin® Prolonged Release Tablets**:

- Dry mouth, loss of appetite, indigestion, abdominal pain or discomfort, diarrhoea;
- Headache, confusion, a feeling of unusual weakness, dizziness, anxiety, nervousness, twitching, difficulty in sleeping, abnormal thoughts or dreams;
- Difficulty in breathing or wheezing, shortness of breath, decreased cough reflex;
- Rash, itchy skin;
- Sweating, chills.

Uncommon side effects

(Probably affecting fewer than 1 in 100 people taking **OxyContin® Prolonged Release Tablets**)

- Difficulty in swallowing, belching, hiccups, wind, gastrointestinal disorders (e.g. upset stomach), changes in taste;
- A feeling of dizziness or 'spinning', a feeling of 'faintness' especially on standing up, hallucinations, mood changes, depression, a feeling of extreme happiness, restlessness, agitation, generally feeling unwell, loss of memory, shaking, difficulties with speech, reduced sensitivity to pain or touch, tingling or numbness, seizures, fits or convulsions, blurred vision;
- Difficulty in passing urine, impotence, decreased sexual drive, absence of menstrual periods;
- Fast heart beat, low blood pressure, flushing of the skin;
- Dehydration, thirst, swelling of the hands, ankles or feet;
- Dry skin, severe flaking or peeling of the skin;
- Redness of the face, reduction in size of the pupils in the eye, muscle spasm, high

temperature;

- A need to take increasingly higher doses of **OxyContin® Prolonged Release Tablets** to gain the same level of pain relief (tolerance);
- Withdrawal symptoms such as agitation, anxiety, palpitations, shaking or sweating upon stopping taking **OxyContin® Prolonged Release Tablets**.

Uncommonly, **OxyContin® Prolonged Release Tablets** may affect the results of blood tests to check that your liver is working properly.

Not all side-effects reported for OxyContin® Prolonged Release Tablets are included in this leaflet. Should any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please consult your doctor, pharmacist or other healthcare professional for advice.

6. HOW TO STORE OxyContin® Prolonged Release Tablets

Keep out of the reach and sight of children.

Store below 25 ºC. Store in original package in the outer carton in order to protect from light.

Do not use **OxyContin® Prolonged Release Tablets** after the expiry date which is stated on the blister and carton after “Expiry date”. The expiry date refers to the last day of that month.

7. PRESENTATION OF OxyContin® Prolonged Release Tablets

OxyContin® 5 mg Prolonged Release Tablets are supplied in clear PVC and aluminium foil blister packs of 28.

OxyContin® 10 mg Prolonged Release Tablets are supplied in clear PVC and aluminium foil blister packs of 28.

OxyContin® 20 mg Prolonged Release Tablets are supplied in clear PVC and aluminium foil blister packs of 28.

OxyContin® 40 mg Prolonged Release Tablets are supplied in clear PVC and aluminium foil blister packs of 28.

OxyContin® 80 mg Prolonged Release Tablets are supplied in clear PVC and aluminium foil blister packs of 28.

8. IDENTIFICATION OF OxyContin® Prolonged Release Tablets

OxyContin® 5 mg Prolonged Release Tablets are pale blue, round, bi-convex, film coated tablets, imprinted with OC on one side and 5 on the other side.

OxyContin® 10 mg Prolonged Release Tablets are white, round, bi-convex, film coated tablets, imprinted with OC on one side and 10 on the other side.

OxyContin® 20 mg Prolonged Release Tablets are pink, round, bi-convex, film coated tablets, imprinted with OC on one side and 20 on the other side.

OxyContin® 40 mg Prolonged Release Tablets are yellow, round, bi-convex, film coated tablets, imprinted with OC on one side and 40 on the other side.

OxyContin® 80 mg Prolonged Release Tablets are green, round, bi-convex, film coated tablet, imprinted with OC on one side and 80 on the other side.

9. REGISTRATION NUMBERS

OxyContin® 5 mg Prolonged Release Tablets: 41/2.9/1098

OxyContin® 10 mg Prolonged Release Tablets: 41/2.9/1099

OxyContin® 20 mg Prolonged Release Tablets: 41/2.9/1100

OxyContin® 40 mg Prolonged Release Tablets: 41/2.9/1101

OxyContin® 80 mg Prolonged Release Tablets: 41/2.9/1102

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Mundipharma (Pty) Ltd

P.O. Box 23162

Claremont

7735

South Africa

11. DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET

9 October 2009

® = **OxyContin** is a registered trademark

INLIGTING VIR DIE PASIËNT AANGAANDE

OxyContin® Prolonged Release Tablets

Lees hierdie hele pamflet sorgvuldig deur voordat u hierdie medisyne begin gebruik.

- **Bewaar hierdie pamflet. U mag dit nodig vind om dit weer te lees.**
- **Indien u verdere vrae het , vra asseblief u geneesheer of apteker.**
- **Hierdie medisyne is vir u persoonlik voorgeskryf. Moet nie u medisyne met ander mense deel nie. Dit kan hulle benadeel, al is hul simptome dieselfde as joune.**

SKEDULERINGSTATUS:

S6

EIENDOMSNAAM (en Doseervorme):

OxyContin® 5 mg Prolonged Release Tablets (Tablette)

OxyContin® 10 mg Prolonged Release Tablets (Tablette)

OxyContin® 20 mg Prolonged Release Tablets (Tablette)

OxyContin® 40 mg Prolonged Release Tablets (Tablette)

OxyContin® 80 mg Prolonged Release Tablets (Tablette)

1. WAT BEVAT OxyContin® Prolonged Release Tablets:

Elke **OxyContin® 5 mg Prolonged Release Tablet** bevat 5 mg oksikodoonhidrochloried.

Elke **OxyContin® 10 mg Prolonged Release Tablet** bevat 10 mg oksikodoonhidrochloried.

Elke **OxyContin® 20 mg Prolonged Release Tablet** bevat 20 mg oksikodoonhidrochloried.

Elke **OxyContin® 40 mg Prolonged Release Tablet** bevat 40 mg oksikodoonhidrochloried.

Elke **OxyContin® 80 mg Prolonged Release Tablet** bevat 80 mg oksikodoonhidrochloried.

Daarbenewens bevat **OxyContin® Prolonged Release Tablets** die volgende onaktiewe bestanddele in die tabletkern:

Laktosemonohidraat, Povidoon K30, Ammoniometakrilaat ko-polimeer, Sorbiensuur, Triasetien, Stearielalkohol, Talkum, Magnesiumstearaat.

Die tabletbedekking bevat die volgende bestanddele:

OxyContin® 5 mg Prolonged Release Tablet: Hipromellose (E464), Makrogol 400, Titaniumdioksied (E171), Brilliant Blue (E133) kleurstof.

OxyContin® 10 mg Prolonged Release Tablet: Hipromellose (E464), Hiprolose, Makrogol 400, Titaniumdioksied (E171).

OxyContin® 20 mg Prolonged Release Tablet: Hipromellose (E464), Makrogol 400, Polisorbaat 80, Titaniumdioksied (E171), Ysteroksied (E172)

OxyContin® 40 mg Prolonged Release Tablet: Hipromellose (E464), Makrogol 400, Polisorbaat 80, Titaniumdioksied (E171), Ysteroksied (E172).

OxyContin® 80 mg Prolonged Release Tablet: Hipromellose (E464), Hiprolose, Makrogol 400, Titaniumdioksied (E171), Ysteroksied (E172), Indigo carmine (E132) kleurstof.

2. WAARVOOR WORD OxyContin® Prolonged Release Tablets GEBRUIK:

OxyContin® Prolonged Release Tablets is ‘n sterk analgetikum of “pynstiller” en behoort aan die opioïede groep.

OxyContin® Prolonged Release Tablets word gebruik vir die verligting van matige tot erge pyn by pasiënte met kanker en post-operatiewe pyn, nadat die gastroïntestinale funksie teruggekeer het.

OxyContin® Prolonged Release Tablets word gebruik vir die verligting van erge pyn wat die gebruik van ‘n sterk opioïed analgetikum vereis.

3. VOORDAT OxyContin® Prolonged Release Tablets GENEEM WORD:

Moet nie OxyContin® Prolonged Release Tablets neem

- as u allergies (hipersensitief) is teenoor die aktiewe bestanddeel oksikodoonhidrochloried of enige van die ander bestanddele;
- as u aan erge asemhalingsprobleme met ‘n verlaagde toevoer van suurstof aan die bloed (hipoksie) en/of verhoogde koolstofdioksied versadiging van die bloed (hiperkapnie) ly;
- as u aan ‘n langtermyn (chroniese) obstruktiewe longsiekte ly;
- as u ‘n hartprobleem na langtermyn longsiekte (cor pulmonale) het;
- as u aan langtermyn (chroniese) brongiale asma ly;
- waar die klein derm nie behoorlik werk nie (paralitiese ileum);
- tydens swangerskap en borsvoeding;
- in die teenwoordigheid van erge long-, lewer- of niersiektes;
- indien u ‘n tipe medisyne bekend as monoamienoksidaseïnhibeerders neem of as u hierdie tipe medisyne in die laaste twee weke gebruik het;
- in enige situasie waar opioïede teenaangedui is;
- indien u aan hoofbesering wat erge hoofpyn veroorsaak of u laat siek voel, ly;
- indien u aan erge pyn in u buik ly;
- indien u maag stadiger as wat dit moet ledig (vertraagde gastriese lediging);
- indien u aan voortgesette konstipasie (harde, nie dikwelse stoelgange) ly;
- vir 6 ure voor ‘n operasie of vir die eerste 24 uur na ‘n operasie;
- indien u aan seldsame genetiese probleme van galaktose intoleransie, die Lapp laktase tekort of glukose-galaktose malabsorpsie ly.

Neem spesiale sorg met OxyContin® Prolonged Release Tablets

- by bejaardes of verswakte pasiënte;
- indien u 'n onder-aktiewe tireoïed (hipotireose) het, aangesien u 'n laer dosis van **OxyContin® Prolonged Release Tablets** mag benodig;
- indien u swak adrenale klierfunksie het (Addison's disease);
- indien u prostaat probleme het;
- indien u 'n geestelike afwyking as gevolg van 'n infeksie het (toksiese psigose);
- indien u ooit verslaaf was aan alkohol of geneesmiddels;
- indien u voorheen aan onttrekkingsimptome soos agitasie, angs, bewing of sweet, na die staking van alkohol of geneesmiddels gely het;
- indien u inflammasie van die pankreas (pankreatitis) of probleme met u galblaas het;
- indien u 'n erge hoofpyn het of siek voel aangesien dit mag aandui dat die drukking in u skedel verhoog is;
- indien u lae bloeddruk (hipotensie) of lae bloedvolume (hipovolemie) het;
- indien u inflammatoriese ingewandsiekte het.

Indien hierdie inligting op u van toepassing is of voorheen op u van toepassing was, gesels asseblief met u geneesheer.

Gebruik OxyContin® Prolonged Release Tablets met spesiale sorg in gevalle waar u aan alkohol of geneesmiddels verslaaf is of ooit was.

OxyContin® 80 mg Prolonged Release Tablets

OxyContin® 80 mg Prolonged Release Tablets moet nie deur pasiënte geneem word, wat nog nooit opioïede vantevore geneem het nie, aangesien hul potensie tot lewensbedreigende respiratoriese depressie in hierdie groep van pasiënte kan lei.

Kinders en Adolessente jonger as 18 jaar

OxyContin® Prolonged Release Tablets is nie by kinders en adolessente jonger as 18 jaar getoets nie. Daarom is veiligheid en effektiwiteit nie vasgestel nie en **OxyContin® Prolonged Release Tablets** word nie by kinders en adolessente jonger as 18 jaar aanbeveel nie.

Bejaarde persone

By bejaarde pasiëte sonder lewer- en/of niersiekte, is ‘n dosisaanpassing gewoonlik nie nodig nie.

Neem van ander medisyne

Lig asseblief u geneesheer of apteker in, indien u nou of onlangs enige ander medisyne, insluitend medisyne sonder 'n voorskrif, geneem het. Indien u **OxyContin® Prolonged Release Tablets** saam met ander medisyne gebruik kan die effek van **OxyContin® Prolonged Release Tablets** of die ander medisyne verander.

OxyContin® Prolonged Release Tablets moet nie gelyktydig saam met ‘n tipe medisyne bekend as monoamienoksidaseïnhibeerder (voorbeelde sluit in tranielsipromien, fenelsien, isokarboksied, moklobemied en linesolied) geneem word nie, of as u hierdie tipe medisyne in die laaste twee weke geneem het.

Lig u geneesheer of apteker in:

- indien u medisyne neem om u te help slaap (byvoorbeeld kalmeermiddels, hipnotika of sedeermiddels);
- indien u onlangs anestetika gekry het;
- indien u medisyne neem om depressie te behandel;
- indien u medisyne neem om psigiatriese- of geestesafwykings te behandel;
- indien u ander sterk analgetika of “pynstillers” neem;

- indien u spierverslappers neem;
- indien u medisyne neem om hoë bloeddruk te behandel;
- indien u kinidien neem ('n medisyne om vinnige hartsnelheid te behandel);
- indien u simetidien neem ('n medisyne vir maagsere, slegte spysvertering of sooibrand);
- indien u antifungus medisyne neem (soos ketokonasool);
- indien u antibiotika neem (soos eritromisien).

Neem van OxyContin® Prolonged Release Tablets saam met voedsel en drank.

U kan **OxyContin® Prolonged Release Tablets** met of sonder voedsel neem.

Drink van alkohol tydens u behandeling met **OxyContin® Prolonged Release Tablets** kan u slaperig maak. Indien u geaffekteer word moet u dit vermy om alkohol te drink.

Swangerskap en borsvoeding

Moet nie **OxyContin® Prolonged Release Tablets** tydens swangerskap gebruik nie.

Die aktiewe bestanddeel oksikodoon word oor die plasenta vervoer na die organisme van die kind. Die langtermyn gebruik van **OxyContin® Prolonged Release Tablets** tydens swangerskap kan tot onttrekkingsimptome by pasgebore babas lei. Indien tydens geboorte geneem word, kan asemhalingsprobleme by die kind voorkom.

Moet nie **OxyContin® Prolonged Release Tablets** tydens periodes van borsvoeding neem nie, aangesien die aktiewe bestanddeel oksikodoon in borsmelk kan versprei.

Vra u geneesheer of apteker vir advies voordat enige medisyne geneem of gebruik word.

Bestuur en gebruik van masjienerie

U kan slaperig voel wanneer u OxyContin® Prolonged Release Tablets begin gebruik, of wanneer u na 'n hoër dosis oorskakel. Indien u geaffekteer word moet u nie bestuur of masjienerie gebruik nie.

Belangrike inligting aangaande sommige van die bestanddele van OxyContin® Prolonged Release Tablets

OxyContin® Prolonged Release Tablets bevat laktose. Indien u geneesheer u ingelig het dat u 'n intoleransie teenoor sommige suikers het, kontak u geneesheer voordat u **OxyContin® Prolonged Release Tablets** neem.

4. HOE OM OxyContin® Prolonged Release Tablets TE NEEM

Neem altyd **OxyContin® Prolonged Release Tablets** presies soos deur u geneesheer voorgeskryf. Moet nie u dosis soos deur u geneesheer aanbeveel, oorskry nie. U moet met u geneesheer of apteker nagaan as u nie seker is nie.

Tensy anders voorgeskryf deur u geneesheer, is die gebruiklike dosis vir volwassenes ouer as 18 jaar een **OxyContin® 10 mg Prolonged Release Tablets** (10 mg oksikodoonhidrochloried) met 12 uur intervalle. Sommige pasiënte kan voordeel trek uit 'n dosis van 5 mg om sodoende die newe-effekte te verminder.

U geneesheer sal egter die dosis nodig om u pyn te behandel, voorskryf. Indien u voel dat u steeds in pyn is, of die effek te sterk is terwyl u **OxyContin® Prolonged Release Tablets** neem, bespreek dit met u geneesheer.

Sluk die verlengde vrystellingstablette heel in, om die vrystelling van die aktiewe bestanddeel nie oor 'n verlengde periode van tyd (verlengde vrystelling) te verswak nie.

Sommige pasiënte wat **OxyContin® Prolonged Release Tablets** op 'n vasgestelde tydskedule ontvang, vereis onmiddelike vrystelling pynstillers vir vinnige verligting van deurbraak pyn. **OxyContin® Prolonged Release Tablets** is nie aangedui vir die behandeling van deurbraak pyn nie.

Bejaarde persone

By bejaarde pasiënte sonder nier- en/of lewersiekte, is dosisaanpassings gewoonlik nie nodig nie.

Hoë risiko pasiënte

Pasiënte met nier- en/of lewersiekte wie nie voorheen opioïede ontvang het nie, moet aanvanklik helfte van die aanbevole volwasse dosis neem. Dit is ook van toepassing tot pasiënte met lae liggaamsmassa en pasiënte wat medisyne teen ‘n stadiger snelheid metaboliseer.

Metode van toediening en gebruiksduur

Sluk die verlengde vrystellingstablette heel in sonder om hul te kou en met genoegsame vloeistof (halwe glas water) in die oggend en aand in ooreenstemming met ‘n vasgestelde tydskedule (bv. in die oggend om 8 vm., en in die aand om 8 nm.). U kan **OxyContin® Prolonged Release Tablets** met of sonder voedsel neem.

Ten einde verswakking van die verlengde vrystellingseffek van die tablette te vermy moet die verlengde vrystellingstablette heel ingesluk word en nie toegelaat word om gebreek, gekou of fyngedruk te word nie. Die inname van gebreekte, gekoude of fyngedrukte tablette lei tot spoediger vrystelling van die aktiewe bestanddeel en die absorpsie van ‘n potensieel fatale dosis van die aktiewe bestanddeel oksikodoon (sien onder “Indien u meer **OxyContin® Prolonged Release Tablets** geneem het as wat u moes”).

OxyContin® Prolonged Release Tablets is alleenlik vir mondelingse gebruik (mondelingse inname van heel tablette). Onbehoorlike inspuiting (inspuiting in ‘n bloedvaat) van die opgeloste tablette moet nie gedoen word nie, aangesien dit tot ernstige newe-effekte wat fatal kan wees, lei.

U kan die residu van die tablet in u stoelgang sien. Moet nie bekommer nie, aangesien die aktiewe bestanddeel oksikodoon vroeër vrygestel is terwyl die tablet deur die gastriese sisteem beweeg het en begin het om effektief te wees in u liggaam.

Indien u meer OxyContin® Prolonged Release Tablets geneem het as wat u moet, of as iemand per ongeluk u tablette ingesluk het

Laat weet u geneesheer of hospitaal dadelik. Persone wat 'n oordosis geneem het kan baie slaperig en siek voel. Hulle kan ook moeilike asemhaling hê wat tot bewusteloosheid of selfs dood kan lei, en kan noodbehandeling in 'n hospital benodig. Wanneer mediese hulp gesoek word, maak seker dat u hierdie pamflet en enige oorblywende tablette saam met u neem om u geneesheer te wys.

Indien u vergeet om OxyContin® Prolonged Release Tablets te neem

Indien u 'n kleiner dosis van **OxyContin® Prolonged Release Tablets** as wat voorgeskryf is neem, of as u geheel en al vergeet het om u dosis te neem, kan dit tot onbevredigende en/of onvoldoende pynverligting lei.

Indien u een keer vergeet het om u dosis te neem, kan u dit later neem slegs as die volgende gewone dosis vir meer as 8 uur later geskeduleer is. U kan dan voortgaan om u gewone skedule te volg.

Indien die tyd na die volgende dosis korter is, neem die verlengde vrystellingstablet maar stel die volgende dosis uit met 8 uur.

In prinsiep moet u nooit **OxyContin® Prolonged Release Tablets** meer dikwels as die 8-uurlikse intervalle neem nie.

Moet nooit 'n dubbele hoeveelheid van die enkeldosis neem nie.

Indien u OxyContin® Prolonged Release Tablets staak

Moet nie **OxyContin® Prolonged Release Tablets** staak sonder dat u u geneesheer in kennis gestel het nie.

Indien u die gebruik van u tablette wil staak, bespreek dit eers met u geneesheer. Hulle sal u inlig hoe om dit te doen, gewoonlik deur die dosis geleidelik te verminder sodat u nie onaangename effekte ondervind nie.

Indien u enige verdere vrae oor die gebruik van hierdie produk het, vra u geneesheer of apteker.

5. MOONTLIKE NEWE-EFFEKTE

Soos met alle medisyne kan **OxyContin® Prolonged Release Tablets** newe-effekte veroorsaak, hoewel nie almal dit ondervind nie.

Alle medisyne kan allergiese reaksies veroorsaak, alhoewel ernstige allergiese reaksies seldsaam is. Lig u geneesheer onmiddellik in as u skielike gehyg, moeilike asemhaling, swelling van die ooglede, gesig of lippe, uitslag of gejeuk veral die wat die hele liggaam bedek, kry.

Die mees ernstige newe-effek is ‘n toestand waar u stadiger of swakker asemhaal as wat verwag word (respiratoriese depressie).

Soos met alle sterk pynstillers, is daar ‘n risiko dat u verslaaf of afhanklik kan raak aan **OxyContin® Prolonged Release Tablets**.

Algemene newe-effekte

(Affekteer waarskynlik meer as 1 uit 100 persone wat **OxyContin® Prolonged Release Tablets** neem.)

Meeste mense sal konstipasie kry wanneer hul **OxyContin® Prolonged Release Tablets** neem. U geneesheer kan ‘n purgeermiddel voorskryf om die probleem te oorkom.

U kan siek voel of braak (siek wees) wanneer u hierdie verlengde vrystellingstablette neem, maar dit behoort normaalweg na ‘n paar dae te verdwyn, maar u geneesheer kan ‘n anti-braking medisyne voorskryf indien die probleem voortduur.

U mag vind dat u meer slaperig voel as normaalweg wanneer u begin om u tablette te neem of as die dosis verhoog word. Dit sal verdwyn na ‘n paar dae.

Die volgende newe-effekte is ook algemeen aangemeld by pasiënte wat met **OxyContin® Prolonged Release Tablets** behandel word:

- Droë mond, verlies aan aptyt, slegte spysvertering, buikpyn of -ongemak, diarree;
- Hoofpyn, verwarring, gevoel van ongewone swakheid, duiseligheid, angs, senuweeagtigheid, sametrekkings, moeilik om te slaap, abnormale denke of drome;
- Moeilike asemhaling, gehyg, kortasemheid, verlaagde hoesrefleks;
- Uitslag, jeukerige vel;
- Sweet, koue rillings.

Nie algemene newe-effekte

(Affekteer waarskynlik minder as 1 uit 100 persone wat **OxyContin® Prolonged Release Tablets** neem)

- Moeilike sluk, winde opbreek, hik, gastroïntestinale afwykings (bv. maagongesteldheid), verandering in smaak;
- ‘n Gevoel van duiseligheid of alles wat draai gevoel, gevoel van floute veral as u opstaan, hallusinasie, gemoedsveranderinge, depressie, ‘n gevoel van buitengewone blydskap, rusteloosheid, agitasie, algemene gevoel van ongesteldheid, verlies aan geheue, bewing, moeilike spraak, verlaagde sensitiwiteit teenoor pyn of aanraking, prikkelgevoel of gevoelloosheid, stuipe, stuiptrekkings of konvulsies, dowwe visie;
- Moeilike urien pasering, impotensie, verlaagde seksuele dryf, afwesigheid van

maandstondes;

- Vinnige hartklop, lae bloeddruk, blosing van die vel;
- Dehidrasie, dors, swelling van die hande, enkels, of voete;
- Droë vel, erge afskilfering of vervel van die vel;
- Rooiheid van die gesig, afname in die grootte van die pupille in die oog, spierspasma, hoë temperatuur;
- 'n Nodigheid om toenemend 'n hoër dosis van **OxyContin® Prolonged Release Tablets** te neem om dieselfde vlak van pynverligting (toleransie) te verwerf;
- Onttrekkingsimptome soos agitasie, angs, palpitasies, bewing of sweet met die staking van **OxyContin® Prolonged Release Tablets**.

OxyContin® Prolonged Release Tablets kan die resultate van bloedtoetse om te toets of die lewer ordentlik werk affekteer, maar dit is nie algemeen nie.

Nie al die newe-effekte vir OxyContin® Prolonged Release Tablets aangemeld, is in die pamflet ingesluit nie. Indien enige van die newe-effekte ernstig word, of as u enige newe-effekte wat nie in hierdie pamflet gelys is nie waarneem, raadpleeg u geneesheer, apteker of ander gesondheidsorgspesialis vir advies.

6. HOE OM OxyContin® Prolonged Release Tablets TE BEWAAR:

Bewaar hierdie medisyne buite die bereik en sig van kinders.

Bewaar benede 25 ^{o}C. Bewaar in oorspronkilke verpakking in die kartonhouer om sodoende teen lig te beskerm.

Moet nie **OxyContin® Prolonged Release Tablets** na die vervaldatum wat op die stulpverpakking en karton na "Expiry date" geskryf is, gebruik nie. Die vervaldatum verwys na die laaste dag van die maand.

7. AANBIEDING VAN OxyContin® Prolonged Release Tablets

OxyContin® 5 mg Prolonged Release Tablets word verskaf in deursigtige PVC en aluminium foelie stulpverpakkings van 28.

OxyContin® 10 mg Prolonged Release Tablets word verskaf in deursigtige PVC en aluminium foelie stulpverpakkings van 28.

OxyContin® 20 mg Prolonged Release Tablets word verskaf in deursigtige PVC en aluminium foelie stulpverpakkings van 28.

OxyContin® 40 mg Prolonged Release Tablets word verskaf in deursigtige PVC en aluminium foelie stulpverpakkings van 28.

OxyContin® 80 mg Prolonged Release Tablets word verskaf in deursigtige PVC en aluminium foelie stulpverpakkings van 28.

8. IDENTIFIKASIE VAN OxyContin® Prolonged Release Tablets:

OxyContin® 5 mg Prolonged Release Tablets is vaalblou, ronde, bikonvekse, filmbedekte tablette met OC op een kant en 5 op die ander kant gedruk.

OxyContin® 10 mg Prolonged Release Tablets is wit, ronde, bikonvekse, filmbedekte tablette met OC op een kant en 10 op die ander kant gedruk.

OxyContin® 20 mg Prolonged Release Tablets is pienk, ronde, bikonvekse, filmbedekte tablette met OC op een kant en 20 op die ander kant gedruk.

OxyContin® 40 mg Prolonged Release Tablets is geel, ronde, bikonvekse, filmbedekte tablette met OC op een kant en 40 op die ander kant gedruk.

OxyContin® 80 mg Prolonged Release Tablets is groen, ronde, bikonvekse, filmbedekte tablette met OC op een kant en 80 op die ander kant gedruk.

9. REGISTRASIENOMMERS:

OxyContin® 5 mg Prolonged Release Tablets: 41/2.9/1098

OxyContin® 10 mg Prolonged Release Tablets: 41/2.9/1099

OxyContin® 20 mg Prolonged Release Tablets: 41/2.9/1100

OxyContin® 40 mg Prolonged Release Tablets: 41/2.9/1101

OxyContin® 80 mg Prolonged Release Tablets: 41/2.9/1102

10. NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:

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11. DATUM VAN PUBLIKASIE VAN DIE VOUBILJET:

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® = **OxyContin** is 'n geregistreerde handelsmerk