

**INFORMATION FOR THE PATIENT ABOUT
OxyNorm® Capsules**

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 NAMES (and Dosage Forms):
OxyNorm® 5 mg Capsules (Capsules)
OxyNorm® 10 mg Capsules (Capsules)
OxyNorm® 20 mg Capsules (Capsules)

1. WHAT OxyNorm® Capsules CONTAINS:

Each OxyNorm® 5 mg Capsules contains 5 mg of oxycodone hydrochloride.
Each OxyNorm® 10 mg Capsules contains 10 mg of oxycodone hydrochloride.
Each OxyNorm® 20 mg Capsules contains 20 mg of oxycodone hydrochloride.
In addition OxyNorm® Capsules contain the following inactive ingredients: Microcrystalline cellulose and Magnesium stearate.
The capsule shells contain the following ingredients: Titanium Dioxide (E171), Iron Oxide (E172), Indigo Carmine (E132), Sodium dodecylsulphate and Gelatine. In addition the 5 mg capsules contain Sunset Yellow (E110).

2. WHAT OxyNorm® Capsules ARE USED FOR:

OxyNorm® Capsules are a strong analgesic or "painkiller" and belongs to the group opioids.
OxyNorm® Capsules are used for the relief of moderate to severe pain in patients with cancer and post-operative pain, after gastrointestinal function has returned.
OxyNorm® Capsules are used for the relief of severe pain requiring the use of a strong opioid analgesic.

3. BEFORE TAKING OxyNorm® Capsules:

- Do not take OxyNorm® Capsules
- 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 OxyNorm® Capsules

- with elderly or weakened patients;
 - if you have an under-active thyroid (hypothyroidism), as you may need a lower dose of OxyNorm® Capsules;
 - 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 OxyNorm® Capsules with special caution in cases if you are or ever have been addicted to alcohol or drugs.

Children and Adolescents under 18 years of age

OxyNorm® Capsules have not been tested in children and adolescents under 18 years of age. Therefore safety and efficacy are not established and OxyNorm® Capsules are not recommended in children and adolescents under 18 years of age.

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 OxyNorm® Capsules with some other medicines, the effect of OxyNorm® Capsules or the other medicine may be changed. OxyNorm® Capsules must not be used together with a type of medicine known as a monoamine oxidase inhibitor (examples include tranlycypromide, phenelzine, isocarboxazid, moclobamide 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 OxyNorm® Capsules with food and drink

You can take OxyNorm® Capsules with or without food.
Drinking alcohol during your treatment with OxyNorm® Capsules may make you sleepy. If you are affected you should avoid drinking alcohol.

Pregnancy and breast-feeding

Do not take OxyNorm® Capsules during pregnancy.
The active ingredient oxycodone is transported through the placenta to the organism of the child. The long-term use of OxyNorm® Capsules during pregnancy may lead to withdrawal symptoms in newborn infants. If taken during birth, breathing problems may occur in the child.
Do not take OxyNorm® Capsules during periods of breast-feeding, since the active ingredient 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 OxyNorm® Capsules, 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 OxyNorm® Capsules

The 5 mg capsules contain Sunset Yellow (E110) which may cause allergic reactions.

4. HOW TO TAKE OxyNorm® Capsules:

Always take OxyNorm® Capsules 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 starting dose for adults older than 18 years old is one capsule of OxyNorm® 5 mg Capsules (5 mg oxycodone hydrochloride) every 4 - 6 hours. 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 OxyNorm® Capsules, discuss this with your doctor.
Swallow the capsules whole with water. Do not chew or crush them.
You must only take OxyNorm® Capsules by mouth. The capsule contents should never be injected as this may lead to serious side-effects, which may be fatal.

If you take more OxyNorm® Capsules than you should or if someone accidentally swallows your capsules

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 capsules with you to show to the doctor.

If you forget to take OxyNorm® Capsules

If you miss a dose you should take the next dose as you remember then carry on as before. Do not take two doses within 4 hours.
Do not take a double dose to make up for a forgotten dose.

If you stop taking OxyNorm® Capsules

Do not stop taking OxyNorm® Capsules without telling your doctor.
If you want to stop taking your capsules, 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, OxyNorm® Capsules 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 OxyNorm® Capsules.

Common side effects

(Probably affecting more than 1 in 100 people taking OxyNorm® Capsules)
Most people will have constipation when they take OxyNorm® Capsules. Your doctor can prescribe a laxative to overcome this problem.
You may feel sick or vomit (be sick) when you take these capsules, 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 capsules 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 OxyNorm® Capsules:

- 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 OxyNorm® Capsules)
- 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 OxyNorm® Capsules to gain the same level of pain relief (tolerance);
- Withdrawal symptoms such as agitation, anxiety, palpitations, shaking or sweating upon stopping taking OxyNorm® Capsules.

Uncommonly, OxyNorm® Capsules may affect the results of blood tests to check that your liver is working properly.
Not all side-effects reported for OxyNorm® Capsules are included in this leaflet. Should any of the side effects gets 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 OxyNorm® Capsules:

Keep out of the reach and sight of children.
Store below 30 °C. Store in original package in the outer carton in order to protect from light.
Do not use OxyNorm® Capsules 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 OxyNorm® Capsules:

OxyNorm® 5 mg Capsules are supplied in clear PVDc coated PVC and aluminium foil blister packs of 28.
OxyNorm® 10 mg Capsules are supplied in clear PVDc coated PVC and aluminium foil blister packs of 28.
OxyNorm® 20 mg Capsules are supplied in clear PVDc coated PVC and aluminium foil blister packs of 28.

8. IDENTIFICATION OF OxyNorm® Capsules:

OxyNorm® 5 mg Capsules (capsule size 4) has an orange body and beige cap imprinted with ONR 5 in black ink, and filled with white to off-white powder.
OxyNorm® 10 mg Capsules (capsule size 4) has a white body and beige cap imprinted with ONR 10 in black ink, and filled with white to off-white powder.
OxyNorm® 20 mg Capsules (capsule size 4) has a pink body and beige cap imprinted with ONR 20 in black ink, and filled with white to off-white powder.

9. REGISTRATION NUMBERS:

OxyNorm® 5 mg Capsules: 41/2,9/1103
OxyNorm® 10 mg Capsules: 41/2,9/1104
OxyNorm® 20 mg Capsules: 41/2,9/1105

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

Mundipharma (Pty) Ltd
P O Box 23162, Claremont, 7735

11. DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET:

14 August 2009

® = OxyNorm is a registered trademark

INLIGTING VIR DIE PASIËNT AANGAANDE

OxyNorm® Capsules

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.

SKEDULERINGSSTATUS:

S6

EIENDOMSNAME (en Doseervorme):

OxyNorm® 5 mg Capsules (Kapsules)
OxyNorm® 10 mg Capsules (Kapsules)
OxyNorm® 20 mg Capsules (Kapsules)

1. WAT BEVAT OxyNorm® Capsules:

Elke OxyNorm® 5 mg Capsules bevat 5 mg oksikodoonhidrochloried.
Elke OxyNorm® 10 mg Capsules bevat 10 mg oksikodoonhidrochloried.
Elke OxyNorm® 20 mg Capsules bevat 20 mg oksikodoonhidrochloried.
Daarbenewens bevat OxyNorm® Capsules die volgende onaktiewe bestanddele: Mikrokristallyne sellulose en Magnesiumstearaat.
Die kapsulomhulsel bevat die volgende bestanddele: Titaniumdoksied (E171), Ysteroksied (E172), Indigo Carmine Kleurstof (E132), Natriumdoseselsulfaat en Gelatien. Daarbenewens bevat die 5 mg kapsules Sunset Yellow kleurstof (E110).

2. WAARVOOR WORD OxyNorm® Capsules GEBRUIK:

OxyNorm® Capsules is 'n sterk analgetikum of "pynstiller" en behoort aan die opioïede groep.
OxyNorm® Capsules word gebruik vir die verligting van matige tot erge pyn by pasiënte met kanker en post-operatiewe pyn, nadat die gastroïntestinale funksie terugkeer het.
OxyNorm® Capsules word gebruik vir die verligting van erge pyn wat die gebruik van 'n sterk opioïed analgetikum vereis.

3. VOORDAT OxyNorm® Capsules GENEEM WORD:

- Moet nie OxyNorm® Capsules 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 koolstofdiksied versadiging van die bloed (hiperkapnie) ly;
 - as u aan 'n langtermyn (chroniese) obstruktiwiese longsiekte ly;
 - as u 'n hartprobleem na langtermyn longsiekte (cor pulmonale) het;
 - as u aan langtermyn (chroniese) bronchiale asma ly;
 - waar die klein derm nie behoorlik werk nie (paralitiese ileum);
 - tydens swangerskap en borsvoeding;
 - in die teenwoordigheid van erge long-, lever- of niersiektes;
 - indien u 'n tipe medisyne bekend as monoamienoksidaseinhibeerders 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 OxyNorm® Capsules

- by bejaardes of verswakke pasiënte;
- indien u 'n onder-aktiewe tireoïed (hipotireose) het, aangesien u 'n laer dosis van OxyNorm® Capsules mag benodig;
- indien u swak adrenergiese klierfunksie het (Addison-siekte);
- 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 ingewand siekte het.

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

Gebruik OxyNorm® Capsules met spesiale sorg in gevalle waar u aan alkohol of geneesmiddels verslaaf is of ooit was.

Kinders en Adolesente jonger as 18 jaar

OxyNorm® Capsules is nie by kinders en adolesente jonger as 18 jaar getoets nie. Daarom is veiligheid en effektiwiteit nie vasgestel nie en OxyNorm® Capsules word nie by kinders en adolesente jonger as 18 jaar aanbeveel 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 OxyNorm® Capsules saam met ander medisyne gebruik kan die effek van OxyNorm® Capsules of die ander medisyne verander. OxyNorm® Capsules moet nie gelyktydig saam met 'n tipe medisyne bekend as monoamienoksidaseinhibeerder (voorbeelde sluit in trianiëlsopromed, fenelisin, isokarboksied, moklobamied 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 sedermiddels);
- 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 kindien neem ('n medisyne om vinnige hartsnelheid te behandel);
- indien u simetidien neem ('n medisyne vir maagere, slegte spysvertering of soorbrand);
- indien u antifungus medisyne neem (soos ketokonasool);
- indien u antibiotika neem (soos eritromisien).

Neem van OxyNorm® Capsules saam met voedsel en drank

U kan OxyNorm® Capsules met of sonder voedsel neem.
Drink van alkohol tydens u behandeling met OxyNorm® Capsules kan u slaperig maak. Indien u geaffekteer word moet u dit vermy om alkohol te drink.

Swangerskap en borsvoeding

Moet nie OxyNorm® Capsules tydens swangerskap gebruik nie.
Die aktiewe bestanddeel oksikodoon word oor die plasenta vervoer na die organisme van die kind. Die langtermyn gebruik van OxyNorm® Capsules tydens swangerskap kan tot onttrekkingsimptome by pasgebore babas lei. Indien tydens geboorte geneem word, kan asemhalingsprobleme by die kind voorkom.
Moet nie OxyNorm® Capsules 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 masjinerie

U kan slaperig voel wanneer u OxyNorm® Capsules begin gebruik, of wanneer u na 'n hoër dosis oorskakel.
Indien u geaffekteer word moet u nie bestuur of masjinerie gebruik nie.

Belangrike inligting aangaande sommige van die bestanddele van OxyNorm® Capsules

Die 5 mg kapsules bevat Sunset Yellow kleurstof (E110) wat allergiese reaksies kan veroorsaak.

4. HOE OM OxyNorm® Capsules TE NEEM:

Neem altyd OxyNorm® Capsules presies soos deur u geneesheer voorgeskryf. Moet nie u dosis soos deur u geneesheer aanbeveel, oorskryf nie. U moet met u geneesheer of apteker nagaan as u nie seker is nie.
Tensy anders voorgeskryf deur u geneesheer, is die gebruikelike dosis vir volwassenes ouer as 18 jaar een OxyNorm® 5 mg Capsules (5 mg oksikodoonhidrochloried) elke 4-6 uur. U geneesheer sal egter die dosis benodig om u pyn te behandel voorskryf. Indien u voel dat u steeds in pyn is, of die effek te sterk is terwyl u OxyNorm® Capsules neem, bespreek dit met u geneesheer.
Sluk die kapsules heel in met water. Moet nie hul kou of fyndruk nie.

OxyNorm® Capsules is alleenlik vir mondelinge gebruik. Die kapsulinhoud moet nooit ingespuet word nie, aangesien dit tot ernstige newe-effekte wat fatal kan wees, lei.

Indien u meer OxyNorm® Capsules geneem het as wat u moet of as iemand per ongeluk u kapsules 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 hospitaal benodig. Wanneer mediese hulp gesoek word, maak seker dat u hierdie pamflet en enige oorblywende kapsules saam met u neem om u geneesheer te wys.

Indien u vergeet om OxyNorm® Capsules te neem

Indien u 'n dosis oorgeslaan het, neem die volgende dosis so gou as wat u onthou en gaan dan voort soos voorheen. Moet nie twee dosisse binne 4 ure neem nie. Moet nooit 'n dubbele dosis neem om op te maak vir die vergete dosis nie.

Indien u OxyNorm® Capsules staak

Moet nie OxyNorm® Capsules staak sonder dat u u geneesheer in kennis gestel het nie.
Indien u die gebruik van u kapsules 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 OxyNorm® Capsules 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 gehy, moeilike asemhaling, swelling van die oogdele, gesig of lippe, uitslag of gejeuk veral die wat die hele liggaam bedek, kyt. 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 OxyNorm® Capsules.

Algemene newe-effekte

(Affekteer waarskynlik meer as 1 uit 100 persone wat OxyNorm® Capsules neem)
Meeste mense sal konstipasie kry wanneer hul OxyNorm® Capsules neem. U geneesheer kan 'n purgeermiddel voorskryf om die probleem te oorkom.
U kan siek voel of braak (siek wees) wanneer u hierdie kapsules 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 kapsules 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 OxyNorm® Capsules behandel word:

- Droë mond, verlies aan apyt, slegte spysvertering, buikpyn of -ongemak, diarree;
- Hoofpyn, verwarings, gevoel van ongewone swaakteid, duiseligheid, angs, sensuïteit, sametrekking, moeilik om te slaap, abnormale denke of drome;
- Moeilike asemhaling, gehy, kortasemheid, verlaagde hoëresfere;
- Uitslag, jeukerige vel;
- Sweet, koue rillings;

Nie algemene newe-effekte

(Affekteer waarskynlik minder as 1 uit 100 persone wat OxyNorm® Capsules neem)
• Moeilike sluk, wind opbrek, hik, gastroïntestinale afwykings (bv. maaggesteltheid), verandering in smaak;- 'n Gevoel van duiseligheid of alles wat draai gevoel, gevoel van floute veral as u opstaan, hallusinasie, gemoedsveranderinge, depressie, en gevoel van buitengewone blydskap, rusteloosheid, agitasie, algemene gevoel van ongesteldheid, verlies aan gehoue, bewing, moeilike spraak, verlaagde sensitiviteit teenoor pyn of aanraking, prikkelgevoel of gevoelloosheid, stuip, stuiptrekkings of konvulsies, dowwe visie;
- Moeilike urien pasering, impotensie, verlaagde seksuele dryf, afwesigheid van maandstondes;
- Vinnige hartklop, lae bloeddruk, bloeding van die vel;
- Dehidrasie, dors, swelling van die hande, enkels of voete;
- Droë vel, erge afskliering of vervel van die vel;
- Rooiheid van die gesig, atname in die grootte van die pupille in die oog, spierspasma, hoë temperatuur;
- 'n Nodigheid om toenemend en hoër dosis van OxyNorm® Capsules te neem om dieselfde vlak van pynverligting (toleransie) te verwerf;
- Onttrekkingsimptome soos agitasie, angs, palpitasies, bewing of sweet met die staking van OxyNorm® Capsules.

OxyNorm® Capsules kan die resultate van bloedtoets om te toets of die lever ordentlik werk affekteer, maar dit is nie algemeen nie.
Nie al die newe-effekte vir OxyNorm® Capsules 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 OxyNorm® Capsules TE BEWAAR:

Bewaar hierdie medisyne buite die bereik en sig van kinders.
Bewaar benede 30 °C. Bewaar in oorspronklike verpakking in die kartonhouer om sodende teen lig te beskerm.
Moet nie OxyNorm® Capsules na die vervaldatum wat op die stulpverpakking en karton na "Expiry date" geskryf is, gebruik nie.
Die vervaldatum vermy na die laaste dag van die maand.

7. AANBIEDING VAN OxyNorm® Capsules:

OxyNorm® 5 mg Capsules word verskaf in deursigtige PVDc bedekte PVC en aluminium foelie stulpverpakking van 28.
OxyNorm® 10 mg Capsules word verskaf in deursigtige PVDc bedekte PVC en aluminium foelie stulpverpakking van 28.
OxyNorm® 20 mg Capsules word verskaf in deursigtige PVDc bedekte PVC en aluminium foelie stulpverpakking van 28.

8. IDENTIFIKASIE VAN OxyNorm® Capsules:

OxyNorm® 5 mg Capsules (kapsulegrootte 4) het 'n oranje liggaam en 'n beige dop met ONR 5 in swart ink daarop gedruk en is gevul met wit tot naaswit poeier.
OxyNorm® 10 mg Capsules (kapsulegrootte 4) het 'n wit liggaam en 'n beige dop met ONR 10 in swart ink daarop gedruk en is gevul met wit tot naaswit poeier.
OxyNorm® 20 mg Capsules (kapsulegrootte 4) het 'n pienk liggaam en 'n beige dop met ONR 20 in swart ink daarop gedruk en is gevul met wit tot naaswit poeier.

9. REGISTRASIE-NOMMERS:

OxyNorm® 5 mg Capsules: 41/2.9/1103
OxyNorm® 10 mg Capsules: 41/2.9/1104
OxyNorm® 20 mg Capsules: 41/2.9/1105

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

Mundipharma (Pty) Ltd.
P O Box 23162, Claremont, 7735

11. DATUM VAN PUBLIKASIE VAN DIE VOUBILJET:

14 Augustus 2009

® = OxyNorm is 'n geregistreerde handelsmerk