Package leaflet: Information for the user

Oxypro 15 mg - Oxypro 20 mg - Oxypro 30 mg Oxypro 40 mg - Oxypro 60 mg - Oxypro 80 mg prolonged-release tablets

Active substance: oxycodone hydrochloride

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

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

What is in this leaflet:

1. What Oxypro is and what it is used for

Oxypro is a strong acting painkiller (analgesic) and belongs to the group of opioids. Oxypro is used to treat severe pain, which can be adequately managed only with opioid analgesics. Oxypro is indicated in adults and adolescents aged 12 years and older.

This medicine has been prescribed for you for severe pain, which can be adequately managed only by analgesics. It contains oxycodone which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to you and should not be given to anyone else.

Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you take Oxypro

Do not take Oxypro

- if you are allergic to oxycodone hydrochloride or any of the other ingredients of this medicine (listed in section 6),
- if your breathing is not sufficient; that means significantly shallow or slowed down (severe respiratory depression),
- if you suffer from severe chronic obstructive lung disease associated with obstruction of the airways (COPD),
- if you suffer from cor pulmonale (heart problems after long term lung disease),
- if you suffer from severe bronchial asthma,
- if you suffer from intestinal paralysis, a condition in which the intestine has stopped working (paralytic ileus).

Warnings and precautions

Talk to your doctor or pharmacist before taking Oxypro

- if you are older and debilitated,
- if you have severe lung problems,
- if your liver or kidney function is impaired,
- if you have a thyroid disease where the skin on the face and limbs is pasty, swollen, cool and dry,
- if your thyroid produces an insufficient amount of hormones (called underactive thyroid or hypothyroidism),
- if you have poor adrenal gland function (your adrenal gland is not working properly) for example Addison's disease,
- if you have an enlarged prostate gland, which causes difficulty in passing urine,
- if you suffer with psychosis caused by alcohol or have a mental disorder as a result of an infection (toxic psychosis),
- if you are an alcoholic,
- if you have or had a dependency on strong painkillers (opioids),
- if you suffer from inflammation of the pancreas (which causes severe pain in the abdomen and back), problems with your gall bladder or bile duct,
- if you have colicky abdominal pain or discomfort,
- if you have an obstructive or inflammatory bowel disorder,
- if your doctor suspects that you have intestinal paralysis (a condition where your bowel has stopped working),
- if you have a severe headache or feel sick as this may indicate that the pressure in your skull is increased,
- if you suffer from disturbances of circulatory regulation,
- if you suffer from epilepsy or have a seizure tendency,
- if you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs,
- if you take medicines for the treatment of depression (MAO inhibitors), e.g. tranylcypromine, phenelzine, isocarboxazid, moclobemide or linezolid, or you have taken this type of medicine in the last two weeks,
- if you suffer from constipation,
- if you feel you need to take more Oxypro to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

Tolerance, dependence and addiction

This medicine contains oxycodone which is an opioid medicine. Repeated use of opioid painkillers can result in the drug being less effective (you become accustomed to it, known as tolerance).

Taking this medicine regularly, particularly for a long time, can 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. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

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.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent or addicted to Oxypro 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.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Sleep-related breathing disorders
Oxypro can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (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, contact your prescriber. A dose reduction may be considered by your prescriber.

Talk to your doctor if any of these conditions apply to you.

The most significant risk of overdose of opioids is slow and shallow breathing (respiratory depression). This is most likely to occur in elderly and debilitated patients and may also cause a drop in blood pressure. This could lead to fainting.

Only for 60mg and 80mg prolonged-release tablets:
Do not take Oxypro 60 mg and 80 mg prolonged-release tablets if you have not taken opioids before, these strengths may lead to a life-threatening flattening and slowing down of breathing (respiratory depression).

This medicine has been specially formulated to release the active substance over a 12-hour period. Oxypro prolonged-release tablets are not allowed to be divided, chewed or crushed. This would lead to a potentially lethal dose of the active substance oxycodone hydrochloride (see under "If you take more Oxypro tablets than you should or if someone accidentally swallows your tablets").

When used for a long time (chronic) tolerance to the effects may appear and you may require progressively higher doses of Oxypro to maintain pain control. Do not change the dosage without consulting your prescriber.

Opioids are not the first choice treatment for pain not related to cancer and are not recommended as the only treatment. Other medicines should be used together in the treatment of chronic pain along with opioids. Your prescriber should monitor you closely and make any necessary adjustments to your dose while you are taking Oxypro to prevent addiction and abuse.

Prolonged use of Oxypro may lead to physical dependence. If treatment is stopped abruptly, withdrawal symptoms may occur such as yawning, abnormal dilation of the pupils, tear disorder, runny nose, shaking, sweating, anxiety, convulsions, difficulty sleeping or muscle pain. When you no longer require therapy with Oxypro, it may be advisable for your prescriber to taper the dose gradually.

The active substance oxycodone hydrochloride, similar to other strong opioids (strong painkillers) has a primary dependence potential.

Developing psychological dependence may be possible. In cases of present or past abuse of alcohol or medicines, Oxypro must be used with special caution only.

If you notice any of the following signs whilst taking Oxypro, it could be a sign that you have become dependent or addicted.
– You need to take the medicine for longer than advised by your prescriber
– 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 prescriber 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 Oxypro").

Especially in high dosages you may experience increased sensitivity to pain (hyperalgesia) despite the fact that you are taking increasing doses of Oxypro. Your prescriber will decide whether you need a change in dose or a change in strong analgesic (opioids).

Oxypro are for oral use only (swallowing of whole tablets). The prolonged-release tablets should not be dissolved and injected, as this can cause serious, possibly fatal consequences.

If you are going to have an operation, please tell the doctor at the hospital that you are taking Oxypro.

Similar to other opioids, oxycodone can affect the normal production of the body's hormones (such as cortisol or sex hormones). This happens especially if you have received high doses over long periods of time.

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

Children (under 12 years of age)

Safety and efficacy have not been established in children under 12 years of age. Therefore, Oxypro is not recommended in children under 12 years of age.

Anti-doping warning

The use of Oxypro may lead to positive results in doping controls. Use of Oxypro as a doping agent may become a health hazard.

Other medicines and Oxypro

Tell your prescriber if you are taking/using, have recently taken/used or might take/use any other medicines, including medicines obtained without a prescription.

Use of opioids including Oxypro and sedative medicines such as benzodiazepines or related drugs together increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However, if your prescriber does prescribe Oxypro together with sedative medicines, the dose and duration of concomitant treatment should be limited by your prescriber.

Please tell your prescriber about all sedative medicines you are taking and follow your prescriber's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your prescriber when experiencing such symptoms.

Side effects of Oxypro may occur more frequently or more severely if you use Oxypro concomitantly with medicines that may interfere with the brain function or are used to treat allergies, motion sickness or vomiting. Side effects may occur e.g. flattening and slowing down of breathing (respiratory depression), constipation, dry mouth or disorders in urination.

The risk of side effects increases if you use antidepressants (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine). These medicines may interact with oxycodone and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, and body temperature above 38°C. Contact your prescriber when experiencing such symptoms.

Please tell your prescriber if you are taking any of the following medicines:

- medicines to help you sleep or stay calm (for example hypnotics or sedatives including benzodiazepines)
- medicines to treat depression (for example paroxetine or amitriptyline) including those medicines belonging to the group of MAO-inhibitors (such as tranylcypromine, phenelzine, isocarboxazid, moclobemide or linezolid)
- medicines for allergies, motion sickness or vomiting (antihistamines, antiemetics)
- medicines to treat psychiatric or mental disorders (such as psychotropic drugs, phenothiazines or neuroleptic drugs)
- medicines for the treatment of epilepsy, pain and anxiety, such as gabapentin and pregabalin
- muscle relaxants for the treatment of muscle cramps (such as tizanidine)
- medicines to treat Parkinson's disease
- other strong acting painkillers (opioids)
- cimetidine (a medicine for stomach ulcers, indigestion or heartburn)
- medicines to treat fungal infections (such as ketoconazole, voriconazole, itraconazole, or posaconazole)
- medicines used to treat infections (such as clarithromycin, erythromycin or telithromycin)
- medicines from the group of protease inhibitors to treat HIV (such as boceprevir, ritonavir, indinavir, nelfinavir or saquinavir)
- rifampicin to treat tuberculosis
- carbamazepine (a medicine to treat epilepsy or seizures and certain pain conditions)
- phenytoin (a medicine to treat seizures, fits or convulsions)
- the medical plant St John's Wort (also known as hypericum perforatum)
- quinidine (medicine to treat cardiac arrhythmias)
- certain medicines to prevent your blood clotting or to help thin your blood (e.g. phenprocoumon)

Oxypro with food, drink and alcohol

Drinking alcohol whilst taking Oxypro may make you feel more sleepy and increases the risk of serious side effects such as shallow breathing with a risk of stopping breathing, and loss of consciousness. It is recommended not to drink alcohol while you are taking Oxypro. While taking Oxypro you should avoid drinking grapefruit juice.

Pregnancy and breast-feeding

Pregnancy
Do not take Oxypro if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby. If you use Oxypro during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

There is limited data on the use of oxycodone in humans during pregnancy.

Prolonged use of oxycodone during pregnancy can cause withdrawal symptoms in the newborn. Use of oxycodone during childbirth can cause shallow and slowed down breathing (respiratory depression) in your newborn.

Breast-feeding
Do not take Oxypro while you are breastfeeding as oxycodone passes into breast milk and will affect your baby.

Driving and using machines

Oxypro may impair the ability to drive or operate machinery. This is particularly likely at the beginning of therapy with Oxypro, after increasing the dose, after a change of the medicinal preparation as well as the interaction of Oxypro with alcohol or medicinal products which may impair brain function.

These tablets may cause a number of side effects such as drowsiness which could affect your ability to drive or use machinery (see section 4 for a full list of side effects). These are usually most noticeable when you first start taking the tablets, or when changing to a higher dose. If you are affected you should not drive or use machinery.

This medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive while you have this medicine in your body over a specified limit unless you have a defence (called the 'statutory defence').
- This defence applies when:
  - The medicine has been prescribed to treat a medical or dental problem; and
  - You have taken it according to the instructions given by the prescriber and in the information provided with the medicine.
  - Please note that it is still an offence to drive if you are unfit because of the medicine (i.e. your ability to drive is being affected).

Details regarding a new driving offence concerning driving after drugs have been taken in the UK may be found here: https://www.gov.uk/drug-driving-law.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Oxypro contains lactose

These tablets contain lactose which is a form of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your prescriber before taking Oxypro.

3. How to take Oxypro

Before starting treatment and regularly during treatment, your prescriber will discuss with you what you may expect from using Oxypro, how long the course of tablets will last, when and how long you will need to take it and when to contact your prescriber. They will arrange a plan for stopping treatment (see also "If you

stop taking Oxypro"). This will outline how to gradually reduce the dose and stop taking the medicine.

Always take this medicine exactly as your prescriber has told you. Check with your prescriber if you are not sure.

Dosage

Your prescriber will determine how much Oxypro you should take and how the total daily dose should be divided. Your prescriber will adjust the dose to the intensity of the pain and to your individual sensitivity. Do not change the dosage without consulting your prescriber.

You should receive the lowest effective dose sufficient to relieve your pain. If you have been treated with opioids before, it may be possible that your prescriber may start treatment at higher doses.

A gradual increase of the dose may be necessary if pain relief is insufficient or the pain level increases.

Please talk to your doctor if you suffer from intermittent pain (breakthrough pain) despite pain therapy. Your prescriber may prescribe you an additional analgesic (non-sustained analgesic) to treat breakthrough pain or adjust your dosage with Oxypro. Oxypro is not intended for the treatment of breakthrough pain.

Adults and adolescents (12 years of age and older)

Oxypro prolonged release tablets are available in 5 mg, 10 mg, 15 mg, 20 mg, 30 mg 40 mg, 60 mg and 80 mg strengths.

The usual initial dose is 10 mg oxycodone hydrochloride in 12 hourly intervals.

For the treatment of non-cancer pain a daily dose of 40 mg of oxycodone hydrochloride is generally a sufficient daily dose, but higher dosages may be necessary.

Patients with cancer pain usually require dosages from 80 to 120 mg of oxycodone hydrochloride which may be increased up to 400 mg in individual cases.

Some patients taking Oxypro on a fixed schedule require fast-release painkillers as an on-demand medication to manage breakthrough pain. Oxypro prolonged-release tablets are not intended for the treatment of this breakthrough pain.

Elderly patients

In elderly patients without liver or kidney problems, dosage adjustment is usually not necessary.

Patients with liver or kidney problems

If you suffer from liver or kidney problems and you have not received opioids before, you should receive an initial dose of half of the recommended adult dose.

Other risk patients

If your body weight is low or you have a slower metabolisation rate, and have not taken opioids before, you should initially receive half of the recommended adult dose.

Method of administration

Oral Use

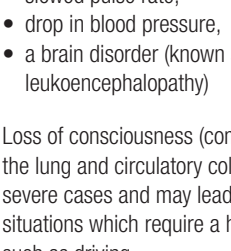
Swallow the prolonged-release tablets whole with a sufficient amount of liquid (½ glass of water) with or without food in the morning and in the evening following a fixed schedule (e.g. at 8 a.m. and 8 p.m.).

You can take Oxypro with or without food.

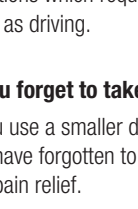
Swallow the prolonged-release tablets as a whole, so that the special prolonged release properties are not affected over a longer period of time. The prolonged-release tablets must be swallowed whole and must not be broken, divided, chewed or crushed.

Opening instructions:

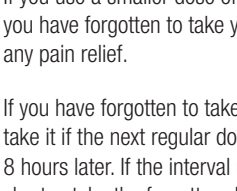
This medicinal product is in child-resistant packaging. The prolonged-release tablets cannot be pressed out of the blister. Please observe the following instructions when opening the blister.



1. Pull off a single dose by tearing along the perforated line on the blister.



2. An unsealed area is exposed/ can be reached by this; this area is at the point where the perforated lines intersect with each other.



3. At the unsealed flap, peel away the cover foil from the bottom foil.

Duration of use

Your prescriber will tell you how long you should take Oxypro.

Do not stop taking Oxypro without consulting your prescriber (see 'if you stop taking Oxypro').

If you are taking Oxypro for a long period of time, your treatment should be monitored and discussed regularly with your prescriber. This is necessary in order to achieve the best pain therapy possible as well as to be able to treat any occurring side effects, to allow a decision on dose adjustment and to decide whether treatment should be continued.

If you feel that the effect of Oxypro is too strong or too weak, talk to your doctor or pharmacist.

If you take more Oxypro tablets than you should or if someone accidentally swallows your tablets

If you have taken more Oxypro than prescribed or someone else has accidentally swallowed your tablets, you should inform your doctor immediately**.**

Overdose may cause:
- narrowed pupils (miosis),
- flattening and slowing down of breathing (respiratory depression),
- somnolence progressing up to stupor (anaesthesia like condition),
- decreased tension of skeletal muscles,
- slowed pulse rate,
- drop in blood pressure,
- a brain disorder (known as toxic leukoencephalopathy)

Loss of consciousness (coma), water retention in the lung and circulatory collapse may occur in more severe cases and may lead to death. Never engage in situations which require a high degree of concentration such as driving.

If you forget to take Oxypro

If you use a smaller dose of Oxypro than prescribed or if you have forgotten to take your dose, you may not feel any pain relief.

If you have forgotten to take your dose once, you may take it if the next regular dose is scheduled more than 8 hours later. If the interval up until the next dose is shorter, take the forgotten dose and take the next dose 8 hours later. You may then continue to follow your usual schedule.

You should never take Oxypro more than once every 8 hours. Please check with your doctor or pharmacist if you are not sure. Never take a doubled amount of a single dose.

If you stop taking Oxypro

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. As with other strong analgesics or painkillers, there is a risk that you may become addicted to Oxypro.

If you experience any of the following significant side effects listed below stop taking Oxypro and contact your doctor immediately.
- Suddenly occurring breathing problems, swelling of the eyelids, face or lips, rash and itching, especially on the whole body – these are signs of severe allergic reactions.
- Slow and depressed breathing (respiratory depression) – this mainly occurs if you are older and debilitated or if you have taken too much Oxypro.
- Severe drop in blood pressure – this may lead to dizziness and fainting (syncope).
- Narrowing of the pupils, cramping of the bronchial muscles (leads to breathlessness) or depression of the cough reflex.

Other possible side effects

Very common (may affect more than 1 in 10 people):

Constipation – this side effect can be counteracted by preventative measures (such as increased drinking of water, nutrition rich in fibre) • vomiting, nausea – especially at the start of treatment. If you experience nausea or vomiting, your doctor may prescribe medication for you • tiredness to drowsiness (sedation) • dizziness • headache.

Common (may affect up to 1 in 10 people):

Pain • diarrhoea • dry mouth • hiccups • indigestion • decreased appetite up to loss of appetite • altered mood and personality • confusion • depression • decreased activity • restlessness • increased activity • nervousness • difficulty in sleeping • abnormal thinking • muscle tremors • lethargy • skin reactions/rash • sweating • pain on micturition • increased urge to urinate • a feeling of unusual weakness, tiredness or fatigue.

Uncommon (may affect up to 1 in 100 people):

Withdrawal symptoms • need to take higher doses of Oxypro to achieve the desired pain relief (tolerance development) • injuries from accidents • allergic reactions (hypersensitivity) • loss of body water (dehydration) • hyperexcitability, mood swings, a feeling of extreme happiness • perception disturbances (e.g. hallucinations, derealisation) • decreased sexual drive • epileptic convulsions (especially in people with epilepsy or a tendency to seizures) • loss of memory, concentration impaired, migraine • increased muscle tension • involuntary muscle contractions • numbness • abnormal coordination • difficulty in speaking • tingling of skin • taste disorder • vision disorders • hearing impaired • a feeling of dizziness or 'spinning' • a fast heartbeat, palpitations • enlarged blood vessels • vocal changes (dysphonia) • cough • oral ulcers • inflammation of the oral mucosa • difficulty in swallowing • wind • belching • intestinal paralysis (a condition where the bowel does not work properly • increased hepatic enzymes • dry skin • inability to fully empty the bladder (urinary retention) • erectile disorder • decreased concentration of sex hormones affecting the sperm production in men or cycle of menstrual period in women • chills • pain (e.g. chest pain) • malaise • water retention (oedema, e.g. in hands, ankles or legs, especially at the ankles) • thirst.

Rare (may affect up to 1 in 1,000 people):

Feeling of faintness, especially on standing up • dark coloured or tarry stools • dental changes • bleeding gums • infections such as cold sores or herpes (which may cause blisters around the mouth or genitals) • increased appetite • hives (urticaria) • weight increase or decrease.

Frequency not known (frequency cannot be estimated from the available data):

Aggression • increased sensitivity to pain • dental caries • biliary stasis • biliary colic • absence of menstrual bleeding • dependence and addiction (see section 2 for signs you may have become dependent or addicted to Oxypro) • sleep apnoea (breathing pauses during sleep) • a problem affecting a valve in the intestines that may cause severe upper abdominal pain (sphincter of Oddi dysfunction).

Drug Withdrawal

When you stop taking Oxypro, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

Long term use of Oxypro during pregnancy may cause life-threatening withdrawal symptoms in the new-born. Symptoms to look for in the baby include irritability, hyperactivity, abnormal sleep pattern, high pitched cry, shaking, being sick, diarrhoea and not putting on weight.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Oxypro

Keep this medicine out of the sight and 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.

Do not use this medicine after the expiry date which is stated on the blister and the carton after "EXP". The expiry date refers to the last day of that month.

Storage conditions

This medicinal product does not require any special storage conditions.

Do not throw away any medicines via wastewater (e.g. not in the toilet or sink). Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Content of the pack and other information

What Oxypro contains

- The active substance is oxycodone hydrochloride.

Oxypro 15 mg prolonged-release tablet:

Each prolonged-release tablet contains 15 mg oxycodone hydrochloride corresponding to 13.5 mg oxycodone. The other ingredients are:
Tablet core: Lactose monohydrate, ammonio methacrylate copolymer, Type B, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate
Tablet coating: Hypromellose, macrogol 400, titanium dioxide (E171), iron oxide black (E172)

Oxypro 20 mg prolonged-release tablet:

Each prolonged-release tablet contains 20 mg oxycodone hydrochloride corresponding to 18 mg oxycodone. The other ingredients are:
Tablet core: Lactose monohydrate, ammonio methacrylate copolymer, Type B, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate
Tablet coating: Hypromellose, macrogol 400, titanium dioxide (E171), iron oxide red (E172)

Oxypro 30 mg prolonged-release tablet:

Each prolonged-release tablet contains 30 mg oxycodone hydrochloride corresponding to 27 mg oxycodone. The other ingredients are:
Tablet core: Lactose monohydrate, ammonio methacrylate copolymer, Type B, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate
Tablet coating: Hypromellose, macrogol 400, titanium dioxide (E171), iron oxide brown (E172), iron oxide black (E172)

Oxypro 40 mg prolonged-release tablet:

Each prolonged-release tablet contains 40 mg oxycodone hydrochloride corresponding to 36 mg oxycodone. The other ingredients are:
Tablet core: Lactose monohydrate, ammonio methacrylate copolymer, Type B, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate
Tablet coating: Hypromellose, macrogol 400, titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172)

Oxypro 60 mg prolonged-release tablet:

Each prolonged-release tablet contains 60 mg oxycodone hydrochloride corresponding to 54 mg oxycodone. The other ingredients are:
Tablet core: Lactose monohydrate, ammonio methacrylate copolymer, Type B, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate
Tablet coating: Hypromellose, macrogol 400, titanium dioxide (E171), iron oxide red (E172), erythrosine (E127)

Oxypro 80 mg prolonged-release tablet:

Each prolonged-release tablet contains 80 mg oxycodone hydrochloride corresponding to 72 mg oxycodone. The other ingredients are:
Tablet core: Lactose monohydrate, ammonio methacrylate copolymer, Type B, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate
Tablet coating: Hypromellose, macrogol 400, titanium dioxide (E171), indigo carmine aluminium lake (E132), iron oxide yellow (E172)

What Oxypro looks like and contents of the pack

Oxypro 15 mg prolonged-release tablets:

Grey, round, biconvex, prolonged-release tablets with a diameter of 6.9 – 7.3 mm and a height of 3.2 – 3.9 mm.

Oxypro 20 mg prolonged-release tablets:

Light pink, round, biconvex, prolonged-release tablets with a diameter of 6.9 – 7.3 mm and a height of 3.2 – 3.9 mm.

Oxypro 30 mg prolonged-release tablets:

Brown, round, biconvex, prolonged-release tablets with a diameter of 6.9 – 7.3 mm and a height of 3.2 – 3.9 mm.

Oxypro 40 mg prolonged-release tablets:

Light orange to ochre, round, biconvex, prolonged-release tablets with a diameter of 6.9 – 7.3 mm and a height of 3.2 – 3.9 mm.

Oxypro 60 mg prolonged-release tablets:

Pink-red, round, biconvex, prolonged-release tablets with a diameter of 8.6 – 9.0 mm and a height of 4.6 – 5.3 mm.

Oxypro 80 mg prolonged-release tablets:

Green, round, biconvex, prolonged-release tablets with a diameter of 8.6 – 9.0 mm and a height of 5.0 - 5.6 mm.

Oxypro is available in child-resistant perforated unit dose blisters in packs of 10, 14, 20, 25, 28, 30, 40, 50, 56, 60, 98 and 100 prolonged-release tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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