

PACKAGE LEAFLET: INFORMATION FOR THE USER

Oxylan 15 mg, 30 mg, 60 mg prolonged-release tablets Oxycodone hydrochloride

This medicine contains Oxycodone hydrochloride which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

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

- 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 only. 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 side effects not listed in this leaflet.

What is in this leaflet:

1. What Oxylan is and what it is used for
2. What you need to know before you take Oxylan
3. How to take Oxylan
4. Possible side effects
5. How to store Oxylan
6. Contents of the pack and other information

1. WHAT OXYLAN IS AND WHAT IT IS USED FOR

Oxylan is a strong painkiller from the group of opioids.

Oxylan is indicated in adults and adolescents (from 12 years and older) for the treatment of severe pain, which can be adequately managed only with opioid analgesics.

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 OXYLAN

Do not take Oxylan

- if you are **allergic** to oxycodone hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you have breathing problems, such as breathing more slowly or more weakly than expected (**respiratory depression**).
- if you have too much **carbon dioxide** in your blood.
- if you suffer from a severe chronic **lung disease** associated with narrowing of the airways (COPD = chronic obstructive pulmonary disease),
- if you have a certain **heart condition** known as cor pulmonale.
- if you have **asthma**.
- if you have a type of bowel obstruction called paralytic ileus.
- if you have acute **severe stomach pain** or suffer from a delayed stomach emptying.

Warnings and precautions

Talk to your doctor or pharmacist before using Oxylan

- if you are **elderly or debilitated** (weak).
- if your **lung, liver or kidney** function is severely impaired.
- if you have a certain disorder of the **thyroid gland** (myxoedema) or if your thyroid gland does not produce enough hormone (underactive thyroid).
- if you have poor adrenal gland function (your adrenal gland is not working properly) for example Addison's disease
- if you are or have ever been **addicted to opioids, alcohol, prescription medicines**, or illegal drugs
- if you have previously suffered from **withdrawal symptoms** such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- if your **prostate** is abnormally enlarged.
- if you are undergoing **alcohol withdrawal treatment**.
- if you have an inflammation of the **pancreas** (pancreatitis) or if you have problems with your **gall bladder**.
- if you have **difficulty or pain passing urine**.
- if your **brain pressure is increased**.
- if you have **low blood pressure** or feel dizzy standing up.
- if you suffer from **epilepsy** or are prone to fits.
- if you are also taking a type of medicine known as **MAO inhibitors** (generally used for the treatment of **depression or Parkinson's disease**).
- if you feel you need to take more of Oxylan 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.

Taking this medicine regularly, particularly for a long time, can lead to addiction (read more under "Tolerance, dependence and addiction" below). 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.

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.

Tolerance, dependence and addiction

Repeated use of opioid pain relievers can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Oxylan can also lead to dependence, abuse and addiction, which may result in life-threatening overdose.

The risk of these side effects can increase with a higher dose and longer duration of use.

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

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

Read more under 'How do I know if I am addicted?' in section 4.

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

Oxylan 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 doctor. A dose reduction may be considered by your doctor.

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.

Anti-Doping Warning

The use of Oxylan may produce positive results in doping controls. Use of Oxylan as a doping agent may be a health hazard.

Other medicines and Oxylan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The risk of side effects is increased if you take Oxylan at the same time as medicines which affect the way the brain works. For example, you may feel very sleepy, or breathing problems may get worse.

Medicines that affect the way the brain works include:

- other strong pain relievers (opioids),
- sleeping pills and tranquillisers,
- antidepressants,
- medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics),
- other medicines which act on the nervous system (phenothiazines, neuroleptics),
- medicines used to treat Parkinson's disease (so-called MAO inhibitors, see also section "Warnings and precautions").

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, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

Concomitant use of Oxylan and sedative medicines such as benzodiazepines or related drugs 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 doctor does prescribe Oxylan together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor'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 doctor when experiencing such symptoms.

Further interactions may occur with

- cimetidine (used to manage excess of gastric acid). It may prolong the duration of effects of Oxylan in your body.
- medicines against blood clotting (e.g. warfarin). Oxylan may influence their effects.
- certain antibiotics, antifungal medicines and medicines containing St. John's Wort.

Oxylan with food and drink and alcohol

Drinking alcohol whilst taking Oxylan may make you feel more sleepy or increase 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're taking Oxylan.

The tablets should be avoided in patients with a history of or present alcohol and drug abuse.

Grapefruit juice may increase the levels of Oxylan in your blood. Check with your doctor if you drink grapefruit juice regularly.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Do not take Oxylan 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 Oxylan during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Breast-feeding

Do not take Oxylan while you are breastfeeding as Oxycodone hydrochloride passes into breast milk and will affect your baby.

Driving and using machines

The 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 if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - 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 or in the information provided with the medicine and
 - It was not affecting your ability to drive safely

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

3. HOW TO TAKE OXYLAN

Your prescriber should have discussed with you, how long the course of tablets will last.

They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

DOSAGE

For doses not realisable/practicable with this strength, other strengths of this medicinal product are available.

Your doctor will adjust your dosage according to pain intensity and to your individual susceptibility.

Please talk to your doctor, if you think that the effect of Oxylan is too weak or too strong.

If not prescribed otherwise by your doctor, the recommended dose is:

- **for adults and adolescents (from 12 years and older):**

The usual starting dose is one 10 mg tablet every 12 hours. In some cases, your doctor may prescribe a starting dose of 5 mg to reduce any side effects you may experience. Your doctor will prescribe the dose required to treat your pain. If you find that you are still in pain whilst taking these tablets, discuss this with your doctor.

- **for children (below 12 years):**

Safety and efficacy of Oxylan have not been tested sufficiently in children under 12 years of age. Therefore, treatment with Oxylan is not recommended in children under 12 years of age.

- **for the elderly (65 years and older):**

Elderly patients with normal liver and/or kidney function may take the same doses as given for adults above.

- **for patients with kidney and/or liver disorders, or with low body weight:**

Your doctor may prescribe a lower starting dose.

For patients who have been **treated with other strong pain relievers (opioids) before**, the doctor may prescribe a higher starting dose.

Your doctor will decide how much you should take every day after that, and how to divide your total daily dose into morning and evening doses. Your doctor will also advise you on any dose adjustments that may become necessary during treatment.

Patients with cancer pain usually require daily dosages between 80 and 120 mg of oxycodone hydrochloride daily. In individual cases, the doctor may increase the dose to up to 400 mg daily.

For the **treatment of non-cancer pain** a daily dose of 40 mg oxycodone hydrochloride is generally sufficient, but higher doses may be needed in some cases.

If you experience pain between doses of Oxylan, you may need to take an additional fast-acting painkiller. Oxylan is **not suitable for this**. Please talk to your doctor if you have this problem.

Your doctor will check your treatment on a regular basis.

METHOD OF ADMINISTRATION

Take the prolonged-release tablets **as a whole with a sufficient amount of liquid** (e.g. ½ glass of water) in the morning and in the evening, **every 12 hours** (for instance, one tablet at 8 o'clock in the morning, and the next one at 8 o'clock in the evening). You can take the tablets with or without food.

Do not break, chew, or crush the tablets. Doing so may cause them to release all their contents into the body at once, which results in a risk of overdose and possibly even death (see also "If you take more Oxylan than you should" below).

If you take more Oxylan than you should

Contact a doctor immediately if you have taken more tablets than you have been prescribed.

Symptoms of overdose are: a reduction in the size of the pupils, breathing problems, feeling weak in the muscles (low muscle tone, hypotonia), and a fall in blood pressure. In severe cases drowsiness or fainting due to a failure of the circulatory system (circulatory collapse), impairment of thinking and of movement, loss of consciousness (coma), reduced pulse rate, accumulation of fluid in the lungs (with symptoms such as difficulty breathing particularly when lying down and a cough productive of frothy sputum which may be pink or bloodstained, excessive sweating, anxiety and pale skin) or a brain disorder (known as toxic leucoencephalopathy) may occur.

Use of **large amounts** of Oxylan **may result in death**.

If you forget to take Oxylan

If you take a smaller dose of Oxylan than prescribed, or if you miss a dose, adequate **pain relief will probably not be achieved**.

If you forget to take one dose, you can take the forgotten dose as soon as you remember it. Please note that you are supposed to take the tablets at 12 hourly (twice daily) intervals.

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

If you stop taking Oxylan

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact a doctor immediately if any of the following symptoms occur:

- **Very slow or weak breathing** (respiratory depression). This is the most serious risk in connection with medicines such as Oxylan (opioids), and may even be fatal after high doses of this medicine.

Other side effects

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

- drowsiness, dizziness, headache.
- constipation, feeling or being sick, vomiting. Your doctor will prescribe an appropriate medicine to treat these symptoms.
- itching.

Common (may affect up to 1 in 10 people)

- changes in mood (anxiety, confusion, depression, nervousness, sleep disorders, abnormal thoughts).
- uncontrolled trembling or shaking movements in one or more parts of your body, feeling weak.
- lowering of blood pressure, rarely accompanied by symptoms such as feeling your heartbeat or fainting.
- difficulty in breathing or wheezing.
- dry mouth, rarely accompanied by thirst and difficulty swallowing, general symptoms of indigestion such as stomach ache, diarrhoea, heartburn.
- decreased appetite.
- rash, heavy sweating.
- sweating, weakness.

Uncommon (may affects up to 1 in 100 people)

- allergic reactions.
- increase in the amount of a certain hormone (ADH = antidiuretic hormone) in the blood with symptoms such as headache, irritability, lethargy, nausea, vomiting, confusion and disturbance of consciousness.
- lack of water in the body (dehydration)
- restlessness, mood swings, hallucinations, euphoric mood, decreased libido.

- amnesia, tingling or numbness (e.g. in the hands or feet), convulsions, increased or decreased muscle tension, tics, reduced sensitivity to pain or touch, , taste changes.
- visual impairment, reduction in the size of the pupils.
- unpleasant sensation irregular and/or forceful beating of the heart, increased pulse rate.
- widening of the blood vessels causing low blood pressure.
- shortness of breath, increased coughing, sore throat, runny nose, voice changes.
- difficulty swallowing, mouth ulcers, sore gums, flatulence (excessive gas in the stomach or bowel), belching, obstruction of the bowel (ileus).
- increased blood levels of certain hepatic enzymes.
- dry skin.
- decreased sexual desire and inability to have or maintain an erection during sexual intercourse.
- chills, feeling sick, injuries due to accidents resulting from decreased alertness, pain (e.g. chest pain), fluid retention (oedema), migraine, thirst, physical dependence with withdrawal symptoms, tolerance.

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

- lymph node disease.
- muscle spasms, epileptic seizures (fits), in particular in patients suffering from epilepsy or with a tendency to seizures.
- low blood pressure.
- bleeding gums, increased appetite, dark-coloured stools, .
- itchy rash, blisters on the skin and the mucous membranes (cold sores or herpes), increased sensitivity to light.
- blood in urine.
- changes in body weight (loss or rise), skin inflammation.

Very rare (may affect up to 1 in 10,000 people)

- speech disorders.
- scaly rash.

Not known (frequency cannot be estimated from the available data)

- sleep apnoea (breathing pauses during sleep)
- severe allergic reactions.
- increased sensitivity to pain.
- cavities or tooth decay.
- Obstructed bile secretion, biliary colic (which causes stomach pain).
- Long term use of Oxylan during pregnancy may cause life-threatening withdrawal symptoms in the newborn. Symptoms to look for in the baby include irritability, hyperactivity and abnormal sleep pattern, high pitched cry, shaking, being sick, diarrhoea and not putting on weight.
- Dependence and addiction (see section “How do I know if I am addicted?”).
- 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 Oxylan, 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.

How do I know if I am addicted?

If you notice any of the following signs whilst taking Oxylan, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use 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, it is important you talk to your prescriber.

Reporting of side effects

If you get any of the 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE OXYLAN

Keep 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.

Do not store above 25°C.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Oxylan contains

The active substance is oxycodone hydrochloride.

Oxylan 15 mg: 1 tablet contains 15 mg oxycodone hydrochloride corresponding to 13.45 mg oxycodone.

Oxylan 30 mg: 1 tablet contains 30 mg oxycodone hydrochloride corresponding to 26.89 mg oxycodone.

Oxylan 60 mg: 1 tablet contains 60 mg oxycodone hydrochloride corresponding to 53.78 mg oxycodone.

The other ingredients are

Tablet core:

Kollidon SR (consisting of poly(vinylacetate); povidone (K = 22.5 - 27.0); sodium lauryl sulphate; silica); cellulose, microcrystalline; colloidal anhydrous silica; magnesium stearate, vegetable.

Tablet coating:

Oxylan 15 mg: polyvinyl alcohol; talc; titanium dioxide (E 171); macrogol 3350; black ferric oxide (E 172), red ferric oxide (E 172), yellow ferric oxide (E 172)

Oxylan 30 mg: polyvinyl alcohol; talc; titanium dioxide (E 171); macrogol 3350; black ferric oxide (E 172), red ferric oxide (E 172), yellow ferric oxide (E 172).

Oxylan 60 mg: polyvinyl alcohol; talc; macrogol 3350; red ferric oxide (E 172).

What Oxylan looks like and contents of the pack

Oxylan 15 mg: grey, round and biconvex film-coated tablets.

Oxylan 30 mg: brown, round and biconvex film-coated tablets.

Oxylan 60 mg: dark red, round and biconvex film-coated tablets.

Oxylan prolonged-release tablets are available in blisters containing 7, 10, 14, 20, 28, 30, 50, 56, 60, 72, 98, and 100 prolonged-release tablets or in unit-dose blisters of 30x1, 50x1, 56x1, 60x1, 72x1, 98x1, and 100x1 prolonged-release tablets.

Not all pack sizes will be marketed.

Marketing Authorisation Holder and Manufacturer

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