

PACKAGE LEAFLET: INFORMATION FOR THE USER

Oxylan 5 mg prolonged-release tablets
Oxylan 10 mg prolonged-release tablets
Oxylan 20 mg prolonged-release tablets
Oxylan 40 mg prolonged-release tablets
Oxylan 80 mg prolonged-release tablets
Oxycodone hydrochloride

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.
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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 (analgesic) from the group of opioids.

Oxylan is used to treat **severe pain**, which requires treatment with an opioid analgesics because other painkillers have not been effective.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE OXYLAN

Do not take Oxylan

- if you are **allergic** to oxycodone hydrochloride, soya, peanut, 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 your adrenal glands are not producing enough hormones (**Addison's disease** or adrenal insufficiency).
- if your **prostate** is abnormally enlarged.
- if you are addicted to **alcohol** or are undergoing alcohol withdrawal treatment.
- if you are, or were previously, **dependent on strong pain killers** (opioids).
- 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**).

Dependence and tolerance

When Oxylan is used for long-term treatment, **tolerance** to the medicine may occur. This means, that you may need a higher dose to achieve the desired pain relief.

Oxylan has a **dependence** potential. If the treatment is stopped too suddenly, withdrawal symptoms such as nausea, vomiting, trembling, vertigo, diarrhoea, sweating or chills, cramps, rapid pulse and high blood pressure may occur. If you no longer need treatment, your doctor will gradually reduce your daily dose.

If this medicine is used as intended in patients suffering from chronic pain states, the risk for physical and psychological dependence is low. Your doctor will weigh the possible risks against the expected benefit. Ask your doctor if you have any questions about this.

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 killers (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").

Concomitant use of <Oxycodone hydrochloride> 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 <Oxycodone hydrochloride> 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

You should not take Oxylan during pregnancy. There are no adequate data from the use of oxycodone in pregnant women. Oxycodone crosses the placenta into the blood circulation of the baby.

Prolonged **use** of oxycodone **during pregnancy** can cause **withdrawal symptoms in newborns**. Infants born to mothers who have received oxycodone during the last 3-4 weeks before labour may experience severe difficulty.

Oxylan should only be used during pregnancy if the benefit outweighs the possible risks to the baby.

Breast-feeding

Oxycodone passes into breast milk and may cause breathing difficulties in the infant. Oxylan should therefore not be used during breast-feeding.

Driving and using machines

Oxylan may impair the ability to drive and use machines.

Oxylan **may impair alertness and reactivity** to such an extent that you may no longer be able to drive or operate tools and machines.

Ask your doctor whether you may drive or operate machines.

Oxylan contains lecithin (soya)

If you are allergic to peanut or soya, do not use this medicinal product.

3. HOW TO TAKE OXYLAN

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

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 (above 12 years):**

The usual starting dose is 10 mg oxycodone hydrochloride every 12 hours.

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

Use in children below 12 years **is not recommended** as the safety and efficacy of Oxylan has not been studied in this age group.

- **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 killers (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 and 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) 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 stop treatment without first speaking with your doctor as **withdrawal symptoms** may occur.

If you do not require treatment with Oxylan anymore, your doctor will advise you on how to **reduce the dose gradually** to prevent the occurrence of withdrawal symptoms.

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

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 (affects more than 1 user in 10)

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

Common (affects 1 to 10 users in 100)

- 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 (affects 1 to 10 users in 1,000)

- 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 (affects 1 to 10 users in 10,000)

- 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.
- soya lecithin may cause allergic reactions.

Frequency unknown (frequency cannot be estimated from the available data)

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- severe allergic reactions.
- increased sensitivity to pain.
- cavities or tooth decay.
- Obstructed bile secretion, biliary colic (which causes stomach pain).

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 national reporting system:

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 OXYLAN

Keep out of the sight and reach of children.

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 5 mg: 1 tablet contains 5 mg oxycodone hydrochloride corresponding to 4.48 mg oxycodone.

Oxylan 10 mg: 1 tablet contains 10 mg oxycodone hydrochloride corresponding to 8.97 mg oxycodone.

Oxylan 20 mg: 1 tablet contains 20 mg oxycodone hydrochloride corresponding to 17.93 mg oxycodone.

Oxylan 40 mg: 1 tablet contains 40 mg oxycodone hydrochloride corresponding to 35.86 mg oxycodone.

Oxylan 80 mg: 1 tablet contains 80 mg oxycodone hydrochloride corresponding to 71.72 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 5 mg: polyvinyl alcohol; talc (E 553b); titanium dioxide (E 171); macrogol 3350; lecithin (soya) (E 322); iron oxide yellow (E 172); iron oxide black (E 172); indigo carmine; aluminium lake (E 132).

Oxylan 10 mg: polyvinyl alcohol; talc (E 553b); titanium dioxide (E 171); macrogol 3350; lecithin (soya) (E 322).

Oxylan 20 mg: polyvinyl alcohol; talc (E 553b); titanium dioxide (E 171); macrogol 3350; lecithin (soya) (E 322); iron oxide yellow (E 172); iron oxide black (E 172); iron oxide red (E 172).

Oxylan 40 mg: polyvinyl alcohol; talc (E 553b); titanium dioxide (E 171); macrogol 3350; lecithin (soya) (E 322); iron oxide yellow (E 172); iron oxide black (E 172); iron oxide red (E 172).

Oxylan 80 mg: polyvinyl alcohol; talc (E 553b); titanium dioxide (E 171); macrogol 3350; lecithin (soya) (E 322); iron oxide yellow (E 172); iron oxide black (E 172); indigo carmine, aluminium lake (E 132).

What Oxylan looks like and contents of the pack

Oxytan 5 mg prolonged-release tablets

Oxytan 5 mg prolonged-release tablets are light grey, round and biconvex film-coated tablets.

Oxytan 10 mg prolonged-release tablets are white, round and biconvex film-coated tablets.

Oxytan 20 mg prolonged-release tablets are pale pink, round and biconvex film-coated tablets.

Oxytan 40 mg prolonged-release tablets are beige, round and biconvex film-coated tablets.

Oxytan 80 mg prolonged-release tablets are pale green, round and biconvex film-coated tablets.

Oxytan 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

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