

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 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.

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 **thyroid disorder** where the skin on the face and limbs is puffy, cool and dry (myxoedema).
- 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 your **prostate** is abnormally enlarged.
- if you have a **mental illness** caused by alcohol or intoxication with other substances.
- 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 an **inflammation of the pancreas** which can cause severe pain in the abdomen or back.
- if your doctor suspects you have **intestinal paralysis** (a condition where the bowel has stopped working).
- if you have **difficulty or pain passing urine**.
- if you have a head injury with severe headache or discomfort – signs your **brain pressure** is **increased**.
- if you have **low blood pressure** or feel dizzy standing up.
- if you have **low blood volume** (hypovolaemia).
- if you suffer from **epilepsy** or are prone to fits.
- if you are taking medicines to treat depression that belong to a group of **MAOIs** (such as tranylcypromine, phenelzine, isocarboxazid, moclobemide or linezolid), or if you have taken them in the last two weeks.
- if you suffer from **constipation**.

Sleep-related breathing disorder

Oxylan can cause sleep-related breathing disorders such as sleep apnea (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.

The most significant threat of opioid overdose is a flattening and slowing of breathing (respiratory depression). This is most likely to occur in the elderly and debilitated patient and can also cause the oxygen level in the blood to decrease. This could lead to e.g. faint.

This medicine is specially formulated to deliver the active substance over a 12 hour period. The prolonged-release tablets must not be broken, divided, chewed or crushed. This would lead to the absorption of a potentially dangerous dose of the active substance oxycodone hydrochloride (see under "If you take more Oxylan than you should or someone else has accidentally swallowed Oxylan").

Tolerance, dependence and addiction

This medicine contains oxycodone, which is an opioid. It can cause dependence and/or addiction.

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. Do not change the dosage without consulting your doctor.

Opioids are not the first choice of treatment for pain not related to cancer and are not recommended as the only treatment. Other medicines should be used in the treatment of chronic

pain along with opioids. Your doctor should monitor you closely and make necessary adjustments to your dose while you are taking Oxylan to prevent addiction and abuse.

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). Repeated use of Oxylan may 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.

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

- You need to take the medicine for longer than advised by your doctor
- 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 doctor 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 Oxylan).

Oxylan has a **dependence** potential. If the treatment is stopped too suddenly, withdrawal symptoms such as yawning, dilated pupils, tearing, runny nose, tremors, sweating, anxiety, restlessness, seizures, insomnia or muscle pain may occur. If you no longer need treatment, your doctor will gradually reduce your daily dose.

Your doctor will weigh the possible risks against the expected benefit. Ask your doctor if you have any questions about this.

The active ingredient oxycodone hydrochloride, like other highly effective opioids (strong pain killers), has potential for abuse. The development of psychological addiction is possible. Oxylan should only be used with particular caution if there has been or has been a history of alcohol, drug or drug abuse.

Particularly in high doses, increased sensitivity to pain (hyperalgesia) can occur, which does not respond to a further increase in the dose of Oxylan. Your doctor will then decide whether to reduce the dose or switch to this strong pain reliever (opioid).

Oxylan is for ingestion only (swallowing as a whole prolonged release tablet). The prolonged-release tablets must not be dissolved and injected, as this can have serious, possibly fatal consequences.

If you need to have an operation, please tell your doctor that you are taking Oxylan.

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**.

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

Children

The safety and effectiveness of Oxylan have not been adequately studied in children under 12 years of age. Therefore, Oxylan is not recommended for children under 12 years of age.

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.

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.

The side effects of Oxylan may become more common or more severe if Oxylan is used at the same time as medicines that can affect brain function or are used to treat allergies, motion sickness or vomiting. Side effects can be, e.g. flattening and slowing of breathing (respiratory depression), constipation, dry mouth or urination problems occur.

The risk of side effects increases if you use antidepressants (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine).

These medicines can interact with oxycodone. You may experience the following symptoms, among others: involuntary, rhythmic muscle contractions, including the muscles that control the movement of the eye, restlessness, excessive sweating, tremors, exaggerated reflexes, increased muscle tension and body temperature above 38 ° C. Contact your doctor if you experience these symptoms.

Please tell your doctor or pharmacist if you are taking any of the medicines from the following list:

- sleeping pills or sedatives (e.g. hypnotics or sedatives, including benzodiazepines)
- medicines for depression (e.g. paroxetine or amitriptyline), including those belonging to a group of MAOIs (such as tranylcypromine, phenelzine, isocarboxazid, moclobemide or linezolid),
- medicines for allergies, motion sickness or vomiting (antihistamines, antiemetics),
- medicines for psychological or mental disorders (such as psychotropic drugs, phenothiazines or neuroleptics),
- Medicines used to treat epilepsy, pain and anxiety such as e.g. gabapentin and pregabalin,

- muscle relaxants used to treat muscle spasms (such as tizanidine)
- medicines used to treat Parkinson's disease,
- other strong pain relievers (opioids),
- cimetidine (a medicine for stomach ulcers, indigestion or heartburn),
- medicines for fungal infections (such as ketoconazole, voriconazole, itraconazole or posaconazole),
- medicines for bacterial infections (such as clarithromycin, erythromycin or telithromycin),
- medicines from the group of protease inhibitors to treat HIV infection (e.g. boceprevir, ritonavir, indinavir, nelfinavir or saquinavir),
- rifampicin for tuberculosis,
- carbamazepine (a medicine for epilepsy or seizures and for certain types of pain),
- phenytoin (a medicine for epilepsy or seizures),
- the medicinal plant St. John's wort (also known as Hypericum perforatum),
- quinidine (a medicine for irregular heartbeat),
- certain medicines to prevent blood clotting or to thin the blood (such as phenprocoumon).

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 (respiratory depression).

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 causes sedation and shallow and slow breathing (respiratory depression) in the breast-fed child. Oxylan should therefore not be used during breast-feeding.

Driving and using machines

Oxylan may impair the ability to drive and use machines. This is to be expected especially at the beginning of therapy with Oxylan, after increasing the dose or after switching preparation, as well as when Oxylan interacts with alcohol or drugs that can impair brain function. In the case of stable therapy, a general driving ban is not necessary. Your attending physician must assess your individual situation.

Oxylan contains lecithin (soya)

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

Oxylan contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per prolonged-release tablet, that is to say essentially 'sodium-free'.

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.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Oxylan, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also if you stop taking Oxylan).

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.

Do not change the dosage without consulting your doctor.

You should be given the lowest effective dose sufficient to relieve your pain.

If you have previously been treated with opioids, your doctor may start your therapy with a higher dose.

It may be necessary to increase the dose gradually if the pain relief is insufficient or if the pain becomes worse.

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 the treatment of cancer pain, 40 mg oxycodone hydrochloride (20mg given twice daily) is generally a sufficient daily dose; however, higher dosages may also be necessary. Patients with tumor pain generally require doses of 80 to 120 mg oxycodone hydrochloride, which can be increased up to 400 mg in individual cases.

Some patients taking Oxylan on a set schedule require fast-acting painkiller as on-demand medication to manage breakthrough pain. Oxylan prolonged-release tablets are not intended for the treatment of these breakthrough pain.

Special populations

- **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:**

If you have liver or kidney problems and you have not yet received opioids, you should start with half the recommended adult dose.

• **Other risk patients:**

If you are light or if your body metabolizes medicines more slowly, the starting dose should be half the recommended adult dose.

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.

Swallow the prolonged-release tablets whole so that the specific release of the active ingredient is not impaired over a longer period of time. The prolonged-release tablets must be swallowed whole and must **not be broken, divided, chewed, or crushed**.

Duration of application

Your doctor will tell you how long to take Oxylan.

Do not stop your Oxylan treatment without talking to your doctor (see "If you stop taking Oxylan").

If you take Oxylan for a long time, you should monitor your therapy and discuss it with your doctor regularly. This is necessary in order to achieve the best possible pain therapy, i.e. to enable timely treatment of occurring side effects as well as a decision on dose adjustment and continuation of treatment.

Please talk to your doctor or pharmacist if you have the impression that the effect of Oxylan is too strong or too weak.

If you take more Oxylan than you should

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

Overdosing can cause:

- constriction of the pupils,
- flattening and slowing of breathing (respiratory depression),
- drowsiness up to absent-mindedness (narcosis-like state),
- decreased tension in the skeletal muscles,
- slowing your pulse,
- drop in blood pressure
- a brain disorder known as toxic leukoencephalopathy.

In more severe cases, unconsciousness (coma), water retention in the lungs and circulatory failure - possibly with fatal outcome - can occur.

Never put yourself in situations that require heightened attention, such as: driving a car

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 a dose, you can take it up if the next regular dose was scheduled in more than 8 hours. If the time to the next dose is shorter, take the missed dose and take the next dose 8 hours later.

You can then continue with your usual intake plan.
In general, you shouldn't take Oxylan more than every 8 hours.
Please ask your doctor or pharmacist if you are not sure

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..

If you stop taking Oxylan, this may trigger withdrawal symptoms (e.g. yawning, dilated pupils, tearing, runny nose, tremors, sweating, anxiety, restlessness, seizures, insomnia or muscle pain). Therefore, it may be advisable for your doctor to reduce the dose gradually
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:

- ◆ Sudden **breathing difficulties, swelling of the eyelids, face or lips, skin rash and itching**, especially all over the body- these are signs of severe allergic reactions.
- ◆ **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.
- ◆ **Drop in blood pressure** - this can cause dizziness and fainting (syncope).
- ◆ **Constriction of the pupils, spasm of the bronchial muscles** (leading to shortness of breath), suppression of the cough reflex.

OTHER SIDE EFFECTS

Very common (affects more than 1 user in 10)

- constipation, this side effect can be counteracted by preventive measures (such as drinking plenty and eating high-fiber diet)
- feeling or being sick, vomiting. Your doctor will prescribe an appropriate medicine to treat these symptoms
- drowsiness, dizziness, headache
- 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
- pain in passing urine, increased urge to urinate

- tiredness or weakness

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

- a need to take increasingly higher doses of Oxylan to gain the same level of pain relief (tolerance)
- injuries due to accidents resulting from decreased alertness
- 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)
- agitation, mood swings, euphoric mood
- perception disorders (e.g. hallucinations)
- decreased libido
- epileptic seizures (especially in individuals with epilepsy or a tendency to have seizures)
- memory loss, concentration disorders, migraines
- increased or decreased muscle tension, tics, tingling or numbness (e.g. in the hands or feet)
- speech disorders, reduced sensitivity to pain or touch, taste changes
- visual impairment, reduction in the size of the pupils
- feeling of spinning or whirling (vertigo)
- unpleasant sensation irregular and/or forceful beating of the heart, increased pulse rate
- widening of the blood vessels causing low blood pressure
- voice changes, increased coughing
- 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
- problems passing urine (urinary retention)
- decreased sexual desire and inability to have or maintain an erection during sexual intercourse
- decrease in the concentration of sex hormones that can affect sperm production in men or the "period" cycle (menstruation) in women.
- chills
- pain (e.g. chest pain), feeling sick
- fluid retention (oedema - e.g. in the hands, ankles, or legs, especially at the ankles), thirst

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
- increased appetite
- increased sensitivity to light
- blood in urine
- skin inflammation
- feeling weak, especially when getting up
- bleeding gums, dark-coloured stools, tooth decay
- itchy rash, blisters on the skin and the mucous membranes (cold sores or herpes)
- changes in body weight (loss or rise)

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

- speech disorders
- scaly rash
- absence of menstrual bleeding

- soya lecithin may cause allergic reactions

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

- aggression
- severe allergic reactions
- sleep apnoea (breathing pauses during sleep)
- 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 new-born. 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.
- a problem affecting a valve in the intestines that may cause severe upper abdominal pain (sphincter of Oddi dysfunction).

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. 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 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

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

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

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

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

Oxylan 80 mg prolonged-release tablets are pale green, 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

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