PACKAGE LEAFLET: INFORMATION FOR THE USER

Oxycodone Lannacher SR 5 mg prolonged-release tablets
Oxycodone Lannacher SR 10 mg prolonged-release tablets
Oxycodone Lannacher SR 20 mg prolonged-release tablets
Oxycodone Lannacher SR 40 mg prolonged-release tablets
Oxycodone Lannacher SR 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.

What is in this leaflet:

1. WHAT Oxycodone Lannacher SR IS AND WHAT IT IS USED FOR

Oxycodone hydrochloride Lanancher is a strong painkiller from the group of opioids.

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

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE Oxycodone Lannacher SR

Do not take Oxycodone Lannacher SR
- 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 Oxycodone Lannacher SR
- 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 Addinson's disease
- 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 Oxycodone Lannacher SR 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.

Oxycodone Lannacher SR 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 Oxycodone Lannacher SR may produce positive results in doping controls.
Use of Oxycodone Lannacher SR as a doping agent may be a health hazard.

Other medicines and Oxycodone Lannacher SR
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 Oxycodone Lannacher SR 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").

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 Oxycodone Lannacher SR 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 Lannacher SR 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 Oxycodone Lannacher SR in your body.
- medicines against blood clotting (e.g. warfarin). Oxycodone Lannacher SR may influence their effects.
- certain antibiotics, antifungal medicines and medicines containing St. John's Wort.

Oxycodone Lannacher SR with food and drink and alcohol
Drinking alcohol whilst taking Oxycodone Lannacher SR 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 Oxycodone Lannacher SR.

The tablets should be avoided in patients with a history of or present alcohol and drug abuse.
Grapefruit juice may increase the levels of Oxycodone Lannacher SR 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 Oxycodone Lannacher SR during pregnancy. There are no adeqaute data from the use of oxycodone in pregnant women.
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 breathing difficulties.
Oxycodone Lannacher SR should only be used during pregnancy if the benefit outweighs the possible risks to the baby.

Breast-feeding
Oxycodone may pass into breast milk and may cause breathing difficulties in the infant. Oxycodone Lannacher SR should therefore not be used during breast-feeding.

Driving and using machines
Oxycodone Lannacher SR may impair the ability to drive and use machines.
Oxycodone Lannacher SR **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.

Oxycodone Lannacher SR contains lecithin (soya)
If you are allergic to peanut or soya, do not use this medicinal product.

3. HOW TO TAKE Oxycodone Lannacher SR

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 Oxycodone Lannacher SR 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 Oxycodone Lannacher SR 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 Oxycodone Lannacher SR, you may need to take and additional fast-acting painkiller.
Oxycodone Lannacher SR 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 Oxycodone Lannacher SR than you should" below).

If you take more Oxycodone Lannacher SR 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 Oxycodone Lannacher SR **may result in death**.

If you forget to take Oxycodone Lannacher SR
If you take a smaller dose of Oxycodone Lannacher SR 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 Oxycodone Lannacher SR
Do not stop treatment without first speaking with your doctor as **withdrawal symptoms** may occur.

If you do not require treatment with Oxycodone Lannacher SR 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 Oxycodone Lannacher SR (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 affect 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.
- 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.
- 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 mainitain 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.
- soya lecithin may cause allergic reactions.

Frequency unknown (frequency cannot be estimated from the available data)
- severe allergic reactions.
- increased sensitivity to pain.
- cavities or tooth decay.
- Obstructed bile secretion, biliary colic (which causes stomach pain),
- Long term use of <Oxycodone hydrochloride> 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.

If you get any of the side effects, talk to your doctor or pharmacist. This includes any possibble side effects not listed in this leaflet.
You can also report side effects directly via the national reporting system:
IMB Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE Oxycodone Lannacher SR

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 Oxycodone Lannacher SR contains

Oxycodone Lannacher SR 5 mg prolonged-release tablets
- **The active substance is** oxycodone hydrochloride. 1 tablet contains 5 mg oxycodone hydrochloride corresponding to 4.48 mg oxycodone.
- **The other ingredients are**
  Tablet core: Kollidon SR (consisting of poly(vinylacetate); povidone (K = 27.0 – 32.4); sodium lauryl sulphate; silica); cellulose, microcrystalline; colloidal anhydrous silica; magnesium stearate, vegetable.
  Tablet coating: 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).

Oxycodone Lannacher SR 10 mg prolonged-release tablets
- **The active substance is** oxycodone hydrochloride. 1 tablet contains 10 mg oxycodone hydrochloride corresponding to 8.97 mg oxycodone.
- **The other ingredients are**
  Tablet core: Kollidon SR (consisting of poly(vinylacetate); povidone (K = 27.0 – 32.4); sodium lauryl sulphate; silica); cellulose, microcrystalline; colloidal anhydrous silica; magnesium stearate, vegetable.
  Tablet coating: polyvinyl alcohol; talc (E 553b); titanium dioxide (E 171); macrogol 3350; lecithin (soya) (E 322).

Oxycodone Lannacher SR 20 mg prolonged-release tablets

- **The active substance is** oxycodone hydrochloride. 1 tablet contains 20 mg oxycodone hydrochloride corresponding to 17.93 mg oxycodone.
- **The other ingredients are**

  Tablet core: Kollidon SR (consisting of poly(vinylacetate); povidone (K = 27.0 – 32.4); sodium lauryl sulphate; silica); cellulose, microcrystalline; colloidal anhydrous silica; magnesium stearate, vegetable.

  Tablet coating: 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).

Oxycodone Lannacher SR 40 mg prolonged-release tablets

- **The active substance is** oxycodone hydrochloride. 1 tablet contains 40 mg oxycodone hydrochloride corresponding to 35.86 mg oxycodone.
- **The other ingredients are**

  Tablet core: Kollidon SR (consisting of poly(vinylacetate); povidone (K = 27.0 – 32.4); sodium lauryl sulphate; silica); cellulose, microcrystalline; colloidal anhydrous silica; magnesium stearate, vegetable.

  Tablet coating: 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).

Oxycodone Lannacher SR 80 mg prolonged-release tablets

- **The active substance is** oxycodone hydrochloride. 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 = 27.0 – 32.4); sodium lauryl sulphate; silica); cellulose, microcrystalline; colloidal anhydrous silica; magnesium stearate, vegetable.

  Tablet coating: 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 Oxycodone Lannacher SR looks like and contents of the pack

Oxycodone Lannacher SR 5 mg prolonged-release tablets

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

Oxycodone Lannacher SR 5 mg 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.

Oxycodone Lannacher SR 10 mg prolonged-release tablets

Oxycodone Lannacher SR 10 mg prolonged-release tablets are white, round and biconvex film-coated tablets.

Oxycodone Lannacher SR 10 mg 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.

Oxycodone Lannacher SR 20 mg prolonged-release tablets

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

Oxycodone Lannacher SR 20 mg 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.

Oxycodone Lannacher SR 40 mg prolonged-release tablets
Oxycodone Lannacher SR 40 mg prolonged-release tablets are beige, round and biconvex film-coated tablets.

Oxycodone Lannacher SR 40 mg 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.

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

Oxycodone Lannacher SR 80 mg 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

This medicinal product is authorised in the Member States of the EEA under the following names:

Austria: Oxycodon G.L. 5/10/20/40/80 mg-Retardtabletten
Germany: Oxypro 5/10/20/40/80 mg Retardtabletten
Ireland: Oxycodone Lannacher SR 5/10/20/40/80 mg prolonged-release tablets
The Netherlands: Oxycodon HCl Lannacher 5/10/20/40/80 mg tabletten met verlengde afgifte
Portugal: Dolanor 5/10/20/40/80 mg comprimido de libertação prolongada
Slovenia: Oxidol 5/10/20/40/80 mg tablete s podaljšanim sproščanjem
United Kingdom: Oxylan 5/10/20/40/80 mg prolonged-release tablets

This leaflet was last approved in 06/2019.