

Package leaflet: Information for the patient

Oxycodone Depot Orion 5 mg prolonged-release tablets
Oxycodone Depot Orion 10 mg prolonged-release tablets
Oxycodone Depot Orion 15 mg prolonged-release tablets
Oxycodone Depot Orion 20 mg prolonged-release tablets
Oxycodone Depot Orion 30 mg prolonged-release tablets
Oxycodone Depot Orion 40 mg prolonged-release tablets
Oxycodone Depot Orion 60 mg prolonged-release tablets
Oxycodone Depot Orion 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 any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Oxycodone Depot Orion is and what it is used for

Oxycodone Depot Orion prolonged-release tablets contain oxycodone hydrochloride. It is a strong painkiller from the group of opioids.

Oxycodone Depot Orion is used in adults and adolescents (from 12 years to 18 years) to treat severe pain, where only opioids give sufficient effect.

2. What you need to know before you take Oxycodone Depot Orion

Do not take Oxycodone Depot Orion

- if you are allergic to oxycodone hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from severely depressed breathing (respiratory depression) with too little oxygen in the blood (hypoxia) and/or too much carbon dioxide (hypercapnia) in the blood
- if you suffer from severe chronic obstructive lung disease (COPD), heart disease due to chronic overload of lung circulation (cor pulmonale) or acute, severe bronchial asthma
- if you suffer from a certain type of blockage in the bowel (paralytic ileus)
- if you have an acute abdomen or suffer from a delayed gastric emptying.

Warnings and precautions

Talk to your doctor or pharmacist before taking Oxycodone Depot Orion

- if you are older or debilitated
- if you have impaired lung function

- if you have impaired kidney function
- if you have impaired liver function
- if you have repeated pauses in breathing when you sleep (sleep apnoea), as this condition may worsen
- if you have reduced thyroid function (hypothyroidism)
- if you have poor adrenal gland function (your adrenal gland is not working properly) for example Addison's disease
- if you suffer from enlargement of the prostate (prostatic hypertrophy)
- if you suffer from a mental illness as a result of an overdose of another medicine (toxic psychosis)
- if you suffer from inflammation of the pancreas (pancreatitis)
- if you have a head injury or increased brain pressure
- if you have low blood pressure (hypotension)
- if you suffer from diseases of the bile duct
- if you suffer from inflammatory bowel diseases
- if you have or often have constipation
- if you have hypovolemia (reduced blood volume)
- if you take medicines that affect brain function, see section 2 "Other medicines and Oxycodone Depot Orion"
- if you take or have recently (within two weeks) taken MAO inhibitors (for the treatment of depression).

Tolerance, dependence and addiction

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

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

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.

Opioids are not first-line treatment for long-term pain that is not caused by cancer, and are not recommended as sole treatment. If you receive this medicine for this type of pain, your doctor will monitor you closely and make necessary dose adjustments to prevent dependence and abuse.

Operations

Inform your doctor that you are taking Oxycodone Depot Orion if you are going to have surgery.

Tolerance

When Oxycodone Depot Orion is used for a long time, tolerance to its effects can mean that increasingly higher doses are required to maintain pain control.

Withdrawal symptoms

Chronic use of Oxycodone Depot Orion may lead to physical dependence and a withdrawal syndrome may occur upon abrupt cessation. When a patient no longer requires therapy with oxycodone, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal (see section 3 "If you stop taking Oxycodone Depot Orion").

Increased sensitivity

An increased sensitivity to pain, which does not respond to an increase in the dose of oxycodone, may occur during treatment with Oxycodone Depot Orion. This is rare, but if it happens, your doctor may lower the dose or switch you to a different opioid.

Sleep-related breathing disorders

Oxycodone Depot Orion 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.

Alcohol

The tablets should not be used together with alcohol. Alcohol can increase the risk of serious side effects such as sleepiness/drowsiness, weakened and slow breathing, unconsciousness, coma and can even be life-threatening.

Children and adolescents

Safety and efficacy of oxycodone has not been investigated in children under 12 years of age. Therefore, use in children under 12 years of age is not recommended.

Other medicines and Oxycodone Depot Orion

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

The risk of side effects increases if you take Oxycodone Depot Orion at the same time as medicines that affect brain function. In such cases, the side effects may be enhanced. For example, fatigue/sleepiness, weakened and slow breathing can worsen and can lead to unconsciousness, coma and can even be life-threatening.

Examples of medicines that affect brain function are:

- Other strong painkillers (opioids)

- Medicines for epilepsy, pain and anxiety (gabapentin and pregabalin)
- Sleeping pills and tranquillisers (sedatives (including benzodiazepines), hypnotics, anxiolytics)
- Medicines for depression
- Medicines for psychiatric or mental illnesses (antipsychotics such as phenothiazines and neuroleptic medicines)
- Medicines used in anaesthesia
- Muscle relaxants used to relieve muscle spasms
- Medicines used to treat allergy, travel sickness or nausea (antihistamines or antiemetics)

Concomitant use of Oxycodone Depot Orion 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 Depot Orion 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 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.

If you take Oxycodone Depot Orion at the same time as medicines (coumarin derivatives) that reduce the blood's ability to clot (coagulate), the clotting time may increase or decrease. It may be necessary to adjust the dose of Oxycodone Depot Orion.

Certain medicines can increase the effect of Oxycodone Depot Orion and therefore a reduction in the dose may be necessary:

- Certain types of antibiotics (macrolide antibiotics)
- Medicines to treat fungal infections
- Protease inhibitors (used to treat HIV)
- Cimetidine (antacid used to treat stomach ulcers and heartburn)

Certain medicines can reduce the effect of Oxycodone Depot Orion and therefore an increase in the dose may be necessary:

- Rifampicin (used to treat tuberculosis)
- Carbamazepine (used in epilepsy and certain pain conditions)
- Phenytoin (used in epilepsy)
- St. John's wort

Oxycodone Depot Orion with food, drink and alcohol

You can take Oxycodone Depot Orion with a meal, but it is not necessary.

Drinking alcohol whilst taking Oxycodone Depot Orion 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. You should not drink alcohol while you are taking Oxycodone Depot Orion.

You should avoid drinking grapefruit juice during your treatment with Oxycodone Depot Orion because it can increase the effect of the medicine.

Pregnancy, breast-feeding and fertility

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

Oxycodone Depot Orion should not be taken in pregnancy unless clearly necessary.

Prolonged use of oxycodone during pregnancy can cause life-threatening withdrawal symptoms in the new-born. Symptoms to look for in the infant are irritability, hyperactivity, high-pitched cry, shaking, being sick and failure to gain weight.

Breast-feeding

You should not take Oxycodone Depot Orion when you are breast-feeding as oxycodone passes into human milk and may cause breathing problems in the breastfed baby.

Driving and using machines

Oxycodone Depot Orion impairs alertness and reactivity. This should be taken into account when increased attention is required, e.g. when driving and using machinery.

Oxycodone Depot Orion contains lactose

Oxycodone Depot Orion contains lactose (as lactose monohydrate) 64 mg (5 mg tablet), 56 mg (10 mg tablet), 51 mg (15 mg tablet), 46 mg (20 mg tablet), 36 mg (30 mg tablet), 25 mg (40 mg tablet), 86 mg (60 mg tablet) and 60 mg (80 mg tablet). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Oxycodone Depot Orion

Always take this medicine exactly as your doctor 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 Oxycodone Depot Orion, 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 Oxycodone Depot Orion”).

The recommended dose is:

Adults and adolescents (from 12 years to 18 years)

The usual initial dose is 10 mg oxycodone hydrochloride in 12 hourly intervals. In some cases, the doctor may prescribe a starting dose of 5 mg to reduce any side effects you may experience. However, your doctor will prescribe the dose required to treat pain.

Patients who have already taken opioids can start treatment with higher dosages taking into account their experience with opioid treatment.

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

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

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

If you have impaired kidney and/or liver function or if you have a low body weight or you are elderly your doctor may prescribe a lower starting dose.

Method of administration

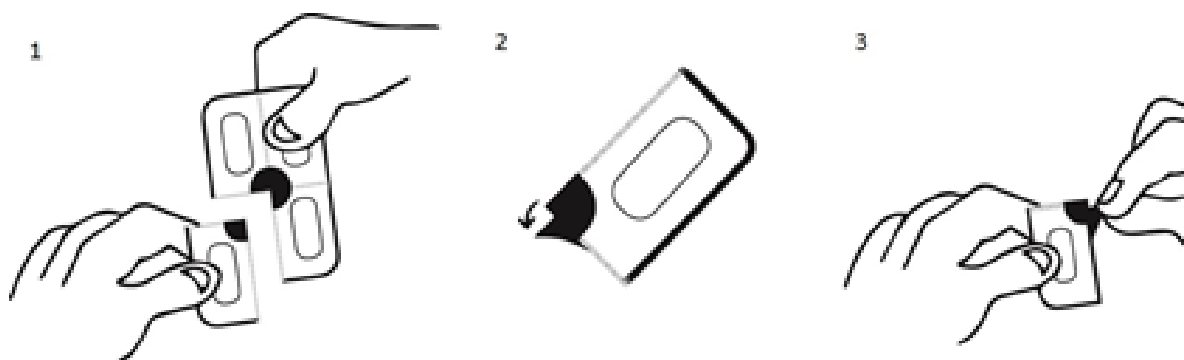
Swallow the prolonged-release tablet whole with a sufficient amount of liquid ($\frac{1}{2}$ glass of water) with or without food in the morning and in the evening following a fixed schedule (e.g. at 8 a.m. and 8 p.m.).

The tablets must be swallowed whole, not chewed, divided or crushed as this leads to rapid oxycodone release due to the damage of the prolonged release properties. The administration of chewed, divided or crushed prolonged-release tablets leads to a rapid release and absorption of a potentially fatal dose of oxycodone (see section “If you take more Oxycodone Depot Orion than you should”).

Oxycodone Depot Orion should not be taken with alcoholic beverages.

Opening instructions:

This medicinal product is in childproof packaging. The prolonged-release tablets cannot be pressed out of the blister. Please follow the opening instruction.



1. Pull off a single dose by tearing along the perforated line on the blister.
2. An unsealed area is exposed/can be reached by this; this area is at the point where the perforated lines intersect with each other.
3. At the unsealed flap, peel away the cover foil from the bottom foil.

Further determination of the daily dose, the division into the single doses and any dose adjustments during the further course of therapy are performed by the treating physician and depend on the previous dosage.

Some patients who receive Oxycodone Depot Orion according to a fixed schedule need rapidly acting painkillers as rescue medication to control breakthrough pain. Oxycodone Depot Orion is not intended for the treatment of breakthrough pain.

The treatment needs to be controlled regularly with regard to pain relief and other effects in order to achieve the best pain therapy possible as well as to be able to treat any occurring side effects in good time and to decide whether treatment should be continued.

If you take more Oxycodone Depot Orion than you should

If you have taken more Oxycodone Depot Orion than prescribed, you must inform your doctor or your local poison control center immediately.

The following symptoms may occur: constricted pupils, depressed breathing (respiratory depression, pulmonary oedema), muscle weakness, a brain disorder (known as toxic leukoencephalopathy), slow pulse and drop in blood pressure. In severe cases, drowsiness and unconsciousness (coma) may occur.

If you forget to take Oxycodone Depot Orion

You can take the forgotten dose but if it is a short time until the next dose, you should skip the missed dose. You can then continue to take this medicine as directed.

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

If you stop taking Oxycodone Depot Orion

Do not stop treatment without informing your doctor.

If use is stopped suddenly after a long period of treatment, withdrawal symptoms such as restlessness, anxiety, insomnia, involuntary muscle contractions, tremors and gastrointestinal problems may occur. Your doctor will tell you how to stop treatment to reduce the risk of withdrawal symptoms, usually by gradually reducing the dose.

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

4. Possible side effects

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

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

Very slow or weak breathing (respiratory depression). This is the most serious risk with medicines such as Oxycodone Depot Orion (opioids) and can even be life-threatening.

Other possible side effects which may occur:

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

- sedation, dizziness, headache
- constipation, nausea, vomiting
- itching.

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

- anorexia, loss of appetite
- several psychological side effects such as changes in mood (e.g. anxiety, depression); changes in activity (mostly sedation, sometimes accompanied by lethargy, occasionally increase with nervousness and insomnia) and changes in performance (thought process disorder, confusion, isolated cases of speech disorders)
- feeling very sleepy (lethargy), trembling (tremor)
- depressed breathing, difficulty in breathing or wheezing (dyspnoea, bronchospasm)
- dry mouth, rarely accompanied by thirst and difficulty swallowing, gastrointestinal disorders such as bellyache, diarrhoea, upset stomach (dyspepsia)
- skin disorders such as rash, increased sweating (hyperhidrosis), rarely increased sensitivity to light (photosensitivity), in isolated cases itchy (urticaria) or scaly rash (exfoliative dermatitis)
- urinary disorders (frequent urination)
- lack of strengths (asthenia), fatigue.

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

- hypersensitivity (allergic reactions)
- a condition which causes abnormal or increased production of a hormone reducing urination
- lack of water in the body (dehydration)
- change in perception such as depersonalisation, hallucinations (perception of things that are not there), emotional instability, abnormally acute sense of hearing (hyperacusis), euphoria, dysphoria, restlessness
- increased and decreased muscle tone, involuntary muscle contractions, disturbance of memory (amnesia), fits, high blood pressure, speech disorder, reduced sense of touch (hypoesthesia), coordination disturbances, fainting, pins and needles (paraesthesia), taste disorder
- lacrimation disorder, visual disturbances, constriction of the pupils
- vertigo (dizziness), tinnitus

- fast or irregular beating of the heart (supraventricular tachycardia, palpitations (in context of withdrawal syndrome), widening of the blood vessels
- increased coughing, inflammation of the throat (pharyngitis), runny nose, voice changes
- oral ulcers, inflammation of the gums, inflamed mouth (stomatitis), impaired ability to swallow (dysphagia), flatulence, belching, obstruction in the gut (ileus)
- increased liver values, ureteral spasm
- dry skin
- urinary retention
- disturbances of sexual function (reduced sexual desire and impotence), reduced hormone production in the testicles/ovaries (hypogonadism)
- accidental injuries, pain (e.g. chest pain), feeling unwell, excessive fluid in the tissues (oedema), swelling of the arms and legs due to fluid accumulation, migraine, physical dependence with withdrawal symptoms, drug tolerance, thirst, chills.

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

- lymph node disease (lymphadenopathy)
- seizures, in particular in patients suffering from epilepsy or with a tendency to seizures, muscle spasms (involuntary contraction of the muscle)
- low blood pressure, tendency to faint when standing up
- gum bleeding, increased appetite, tarry stool, tooth staining and damage
- herpes simplex (disorder of the skin and mucosa), hives (urticaria)
- changes in body weight (loss or rise), cellulitis.

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

- anaphylactic reaction, anaphylactoid reaction
- aggression
- increased sensibility to pain (hyperalgesia)
- dental caries, dental problems
- biliary stasis, biliary colic
- absence of menstrual bleeding (amenorrhoea)
- long-term use of Oxycodone Depot Orion 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
- sleep apnoea (breathing pauses during sleep) (see section 2 "Sleep-related breathing disorders")
- a problem affecting a valve in the intestines that may cause severe upper abdominal pain (sphincter of Oddi dysfunction).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Oxycodone Depot Orion

Keep this medicine out of the sight and reach of children. Store this medicine in a locked safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.

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

[Oxycodone Depot Orion 5 mg]

Do not store above 25°C.

[Oxycodone Depot Orion 10 mg]

Do not store above 25°C.

[Oxycodone Depot Orion 15 mg/20 mg/30 mg/40 mg/60 mg/80 mg]

This medicinal product does not require any special storage conditions.

Do not throw away any 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. Content of the pack and other information

What Oxycodone Depot Orion contains

- The active substance is oxycodone hydrochloride.
5 mg: Each prolonged-release tablet contains 5 mg oxycodone hydrochloride corresponding to 4.5 mg oxycodone.
- The other ingredients are:
Tablet core:
Lactose monohydrate, ammonio methacrylate copolymer, Type B, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate.
Film-coating:
Hypromellose, talc, macrogol 400, titanium dioxide, brilliant blue FCF.

10 mg: Each prolonged-release tablet contains 10 mg oxycodone hydrochloride corresponding to 9 mg oxycodone.
- The other ingredients are:
Tablet core:
Lactose monohydrate, ammonio methacrylate copolymer Type B, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate.
Film-coating:
Hypromellose, talc, macrogol 400, titanium dioxide.

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

20 mg: Each prolonged-release tablet contains 20 mg oxycodone hydrochloride corresponding to 17.9 mg oxycodone.
- The other ingredients are:
Tablet core:
Lactose monohydrate, ammonio methacrylate copolymer Type B, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate
Film-coating:
Hypromellose, talc, macrogol 400, titanium dioxide, iron oxide red.

30 mg: Each prolonged-release tablet contains 30 mg oxycodone hydrochloride corresponding to 26.9 mg oxycodone.
- The other ingredients are:
Tablet core:

Lactose monohydrate, ammonio methacrylate copolymer Type B, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate.

Film-coating:

Hypromellose, talc, macrogol 400, titanium dioxide, iron oxide brown, iron oxide black.

40 mg: Each prolonged-release tablet contains 40 mg oxycodone hydrochloride corresponding to 35.9 mg oxycodone.

- The other ingredients are:

Tablet core:

Lactose monohydrate, ammonio methacrylate copolymer Type B, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate.

Film-coating:

Hypromellose, talc, macrogol 400, titanium dioxide, iron oxide red, iron oxide yellow.

60 mg: Each prolonged-release tablet contains 60 mg oxycodone hydrochloride corresponding to 53.8 mg oxycodone.

- The other ingredients are:

Tablet core:

Lactose monohydrate, ammonio methacrylate copolymer Type B, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate.

Film-coating:

Hypromellose, talc, macrogol 400, titanium dioxide, iron oxide red, erythrosine.

80 mg: Each prolonged-release tablet contains 80 mg oxycodone hydrochloride corresponding to 71.7 mg oxycodone.

- The other ingredients are:

Tablet core:

Lactose monohydrate, ammonio methacrylate copolymer Type B, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate.

Film-coating:

Hypromellose, macrogol 400, titanium dioxide, indigo carmine aluminum lake, iron oxide yellow.

What Oxycodone Depot Orion looks like and contents of the pack

Oxycodone Depot Orion 5 mg prolonged-release tablets:

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

Oxycodone Depot Orion 10 mg prolonged-release tablets:

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

Oxycodone Depot Orion 15 mg prolonged-release tablets:

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

Oxycodone Depot Orion 20 mg prolonged-release tablets:

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

Oxycodone Depot Orion 30 mg prolonged-release tablets:

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

[Oxycodone Depot Orion 40 mg prolonged-release tablets:]

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

Oxycodone Depot Orion 60 mg prolonged-release tablets:

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

Oxycodone Depot Orion 80 mg prolonged-release tablets:

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

Oxycodone Depot Orion is available in child-resistant perforated unit dose blisters with 10x1, 14x1, 20x1, 25x1, 28x1, 30x1, 40x1, 50x1, 56x1, 60x1, 98x1 and 100x1 prolonged-release tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Orion Corporation

Orionintie 1

FI-02200 Espoo

Finland

Manufacturer

Orion Corporation Orion Pharma

Joensuunkatu 7

FI-24100 Salo

Finland

This medicine is authorised in the Member States of the European Economic Area under the following names:

DK: Orionox Depot 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg depottabletter

FI: Oxycorion Depot 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg depottabletit

NO: Orionox Depot

SE: Oxycodone Depot Orion 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg depottabletter

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