

Package leaflet: Information for the patient

Oxycodone hydrochloride Rowex 5 mg Hard capsules
Oxycodone hydrochloride Rowex 10 mg Hard capsules
Oxycodone hydrochloride Rowex 20 mg Hard capsules

oxycodone hydrochloride

For use in adults and adolescents aged 12 years and older

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

1. What Oxycodone hydrochloride Rowex is and what it is used for

Oxycodone hydrochloride Rowex contains the active substance oxycodone hydrochloride which is a strong painkiller of the group of opioids.

Oxycodone hydrochloride Rowex is used in adults and adolescents aged 12 years and older to treat severe pain which can be adequately managed only with opioid analgesics.

2. What you need to know before you take Oxycodone hydrochloride Rowex

Do not take Oxycodone hydrochloride Rowex if you

- are allergic to oxycodone hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- have breathing problems, such as severely depressed breathing (respiratory depression), severe chronic obstructive lung disease, or severe bronchial asthma. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected.
- have elevated carbon dioxide blood levels
- have a heart problem after long-term lung disease (cor pulmonale)
- suffer from intestinal paralysis (paralytic ileus). Signs may be that your stomach empties more slowly than it should (delayed gastric emptying) or you have severe pain in your abdomen.

Warnings and precautions

Talk to your doctor or pharmacist before taking Oxycodone hydrochloride Rowex if you

- are elderly or weakened

- have severely impaired lung function
- have liver or kidney problems
- have a thyroid disorder with dryness, coldness and swelling of the skin affecting the face and limbs (myxoedema)
- have impaired function of the thyroid gland
- suffer from adrenal insufficiency which may cause symptoms including weakness, weight loss, dizziness, feeling or being sick (Addison's disease)
- have an enlarged prostate gland which cause difficulty in passing urine (in men)
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping taking alcohol or drugs
- or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction")
- are a smoker
- have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses
- have a mental disorder as a result of poisoning, e.g. with alcohol (toxic psychosis)
- have inflammation of the pancreas which causes severe pain in the abdomen and back
- have problems with your gall bladder or bile duct
- have an obstructive or inflammatory bowel disease
- have a head injury, severe headache or feel sick as this may indicate that the pressure in your brain is increased
- have low blood pressure
- have low blood volume (hypovolaemia); this can happen with severe bleeding, severe burns, excessive sweating, severe diarrhoea or vomiting
- have epilepsy or a tendency to fits/convulsions
- are taking a type of medicine known as monoamine oxidase (MAO) inhibitors, for the treatment of depression or Parkinson's disease, or have taken them in the last 2 weeks
- are going to have an operation or had an abdominal surgery most recently

Please talk to your doctor if any of these apply to you or if any of these conditions applied to you in the past.

Tolerance, dependence and 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).

Oxycodone hydrochloride Rowex may cause dependency. When used for a long time, tolerance to the effects may occur and progressively higher doses may be required to maintain pain control.

Chronic use of Oxycodone hydrochloride Rowex may lead to physical dependence and a withdrawal syndrome may occur upon abrupt cessation (see section 3. "If you stop taking Oxycodone hydrochloride Rowex". Withdrawal symptoms may include yawning, dilation of the pupil of the eye, abnormal or excessive secretion of tears, running nose, trembling or shaking, increased sweating, anxiety, agitation, fits, sleeplessness and muscle pain.

An increased sensitivity to pain (hyperalgesia) that will not respond to a further dose increase of oxycodone may occur, particularly in high doses. An oxycodone dose reduction or change to an alternative opioid may be required.

Repeated use of Oxycodone hydrochloride Rowex 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 Oxycodone hydrochloride Rowex 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 hydrochloride Rowex, 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 hydrochloride Rowex”).

Oxycodone hydrochloride Rowex should be used with particular care in patients with a history of or present alcohol or drug abuse.

In case of abusive injection (injection in a vein) the capsule excipients may lead to destruction (necrosis) of the local tissue, change of lung tissue (granulomas of the lung) or other serious, potentially fatal events.

Sleep-related breathing disorders

Oxycodone hydrochloride Rowex 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.

Doping

Athletes must be aware that this medicine may cause a positive reaction to ‘anti-doping’ tests. The use of Oxycodone hydrochloride Rowex as a doping agent may become a health hazard.

Children

Oxycodone has not been studied in children under 12 years of age. Therefore, safety and efficacy have not been demonstrated and use of Oxycodone hydrochloride Rowex is not recommended in children under 12 years.

Other medicines and Oxycodone hydrochloride Rowex

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

Taking Oxycodone hydrochloride Rowex at the same time as certain medicines which affect the way the brain works (see below) can enhance the risk for stopping breathing, especially in the case of overdose

and in the elderly, and/or enhance the sedative effect of Oxycodone hydrochloride Rowex (you may feel very sleepy).

Concomitant use of Oxycodone hydrochloride Rowex and medicines which affect the way the brain works (e.g. sedative medicines such as benzodiazepines or related medicines, see below) 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 Rowex 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.

Medicines that affect the way the brain works include:

- other strong pain killers (opioids)
- sleeping pills and tranquillisers (sedative medicines such as benzodiazepines)
- medicines to treat depression, such as paroxetine
- medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics)
- medicines to treat psychiatric or mental disorders (antipsychotics)
- medicines used to treat Parkinson's disease.

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.

Further interactions may occur with:

- certain medicines to prevent your blood clotting or to help thin your blood (known as coumarin anticoagulants, for example warfarin or phenprocoumon). Oxycodone hydrochloride Rowex may influence their effects.
- muscle relaxants
- certain antibiotics (e.g. clarithromycin, erythromycin, telithromycin or rifampicin)
- certain medicines to treat fungal infections (e.g. ketoconazole, voriconazole, itraconazole or posaconazole)
- certain medicines to treat HIV infection (e.g. boceprevir, ritonavir, indinavir, nelfinavir or saquinavir)
- cimetidine, a medicine to treat heartburn
- carbamazepine (a medicine to treat seizures or convulsions/fits and certain pain conditions)
- phenytoin, a medicine to treat seizures
- St. John's wort, a medicine to treat depression
- quinidine (a medicine to treat a fast heartbeat)
- monoamine oxidase inhibitors, or if you have taken this type of medicine in the last two weeks (see section 2 'Warnings and precautions').

Oxycodone hydrochloride Rowex with drink and alcohol

Drinking alcohol whilst taking Oxycodone hydrochloride Rowex 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 hydrochloride Rowex.

Drinking grapefruit juice whilst taking Oxycodone hydrochloride Rowex may increase the risk for side effects. You should avoid drinking grapefruit juice during treatment with Oxycodone hydrochloride Rowex.

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 hydrochloride Rowex during pregnancy. There are limited 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. Use of oxycodone during childbirth can cause breathing problems (respiratory depression) in the newborn.

- **Breast-feeding**

You should not use Oxycodone hydrochloride Rowex when you are breast-feeding as the active substance oxycodone may pass into breast milk and cause drowsiness (sedation) or breathing problems (respiratory depression) in the suckling child.

Driving and using machines

Oxycodone hydrochloride Rowex may impair the ability to drive or operate machines.

General driving restrictions may not apply during stable treatment; your doctor makes this decision based upon the individual situation. Please discuss with your doctor whether or not, or under which conditions you may drive.

Oxycodone hydrochloride Rowex contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially ‘sodium-free’.

3. How to take Oxycodone hydrochloride Rowex

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 hydrochloride Rowex, 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 hydrochloride Rowex”).

The recommended dose is

Adults and adolescents (12 years of age and older)

The recommended initial dose is 5 mg oxycodone hydrochloride every 6 hours.

However, your doctor will prescribe a dose and frequency of intake required to treat your pain.

Please talk to your doctor if you are still in pain even though you are taking the medicine.

Patients with impaired kidney and/or liver function

The usual initial dose is half of the dose recommended for adults. The doctor will prescribe the dose that is most suited to your personal situation, if possible through the use of a more suitable pharmaceutical form.

Method of administration

For oral use only. Oxycodone hydrochloride Rowex must be swallowed whole with plenty of liquid.

Oxycodone hydrochloride Rowex can be taken with or without meals.
Do not take Oxycodone hydrochloride Rowex with alcoholic drinks.

Instructions on the use of child-resistant perforated unit dose blisters:

1. Do not push the capsule directly out of the blister.
2. Tear off one pocket from the blister using the perforation.



3. Carefully pull off the foil on the back of the pocket to open it.



If you take more Oxycodone hydrochloride Rowex than you should

If you have taken more Oxycodone hydrochloride Rowex than prescribed you should inform your doctor or your local poison control center immediately.

Signs of an overdose may be:

- narrowed pupils
- breathing more slowly or weakly (respiratory depression)
- sleepiness progressing up to loss of consciousness
- decreased muscle tone
- slowed pulse rate
- drop in blood pressure
- a brain disorder (known as toxic leukoencephalopathy).

In severe cases, loss of consciousness (coma), water retention in the lung and circulatory collapse may occur, which may be fatal.

Never engage in situations which require a high degree of concentration, such as driving.

If you forget to take Oxycodone hydrochloride Rowex

If you use a smaller dose of Oxycodone hydrochloride Rowex than directed or you miss the intake of a dose, pain relief will consequently be insufficient or cease altogether.

If you have forgotten to take a dose, please follow the instructions below:

- If the next regular dose was scheduled more than 4 hours later: Take the forgotten dose immediately and continue with your usual dosing schedule.
- If your next usual dose is due in less than 4 hours: Take the forgotten dose and wait another 4 hours before taking your next dose. Try to get back in your normal dosing schedule.

Do not take more than one dose within any 4-hour period.

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

If you stop taking Oxycodone hydrochloride Rowex

Do not stop treatment without consulting your doctor first.

If you no longer require therapy with Oxycodone hydrochloride Rowex, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal.

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.

The most common side effects are nausea (especially at the beginning of therapy) and constipation. The side effect constipation may be countered by preventive measures (such as drinking plenty of fluids, nutrition rich in fibre). If you experience nausea or vomiting, your doctor may prescribe medication for you.

Important side effects or signs which you should look out for and what to do if you are affected: Stop taking Oxycodone hydrochloride Rowex and contact a doctor or go to your nearest emergency department immediately if you experience any of the following symptoms.

- sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body. These may be signs of serious allergic reactions.
- a more slow or shallow breathing (respiratory depression). This is the most serious side effect with an overdose of strong painkillers such as oxycodone and it mostly occurs in elderly and weak patients
- a serious drop in blood pressure, with possible signs such as dizziness and fainting.

Possible side effects

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

- drowsiness, sleepiness, dizziness, headache
- constipation, feeling sick (nausea), vomiting
- itchy skin.

Common (may affect up to 1 in 10 people)

- anxiety, depression, decreased activity, restlessness, increased activity, nervousness, difficulty in sleeping, abnormal thinking, confusion, shaking (tremor)
- lack of energy, feeling weak, tiredness
- shortness of breath, wheezing
- dry mouth, hiccups, indigestion, stomach ache, diarrhoea
- decreased appetite up to loss of appetite
- skin rash, increased sweating
- painful urination, increased urge to urinate.

Uncommon (may affect up to 1 in 100 people)

- a condition where you breathe more slowly and weakly than expected (respiratory depression)
- allergic reactions
- lack of water in the body (dehydration)
- agitation, mood swings, a feeling of extreme happiness
- hallucinations, a feeling of altered reality
- vision disturbances, reduction in size of the pupils in the eye
- hearing impaired, a feeling of dizziness or 'spinning'(vertigo)
- change in taste
- increased muscle tension, involuntary muscle contractions, epileptic seizures, convulsions (fits)

- tingling or numbness, reduced sensitivity to pain or touch
- problems with coordination or with keeping one's balance
- loss of memory, concentration impaired, speech disorders
- fainting
- faster heartbeat, feeling your heartbeat (in the context of withdrawal syndrome)
- widening of the blood vessels causing low blood pressure
- coughing, voice changes
- mouth ulcers, sore gums
- wind, difficulty in swallowing, belching
- obstruction of the bowel (ileus)
- decreased sexual desire, impotence, low levels of sex hormones in the blood called hypogonadism (seen in a blood test)
- injuries from accidents
- generally feeling unwell, pain (e.g. chest pain)
- swelling of the hands, ankles or feet (oedema)
- migraine
- drug tolerance
- dry skin
- thirst
- problems passing urine
- chills
- physical dependence including withdrawal symptoms (see section 3 'If you stop taking Oxycodone hydrochloride Rowex)
- increase in liver enzymes (seen in a blood test).

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

- low blood pressure; dizziness, fainting caused by sudden drop in blood pressure when standing up
- bleeding gums, increased appetite, dark-coloured, tarry stools, tooth disorders
- blisters on the skin and the mucous membranes (cold sores or herpes), hives (urticaria)
- changes in body weight (loss or rise).

Frequency not known (frequency cannot be estimated from the available data)

- absence of menstrual bleeding
- serious allergic reaction which causes breathing difficulty or dizziness
- aggression
- increased sensitivity to pain (hyperalgesia)
- dental caries
- biliary colic (which causes stomach pain), biliary congestion
- withdrawal symptoms in newborns
- becoming addicted or reliant on these capsules
- cramping of the smooth muscles
- depression of the cough reflex
- sleep apnoea (breathing pauses during sleep).

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: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Oxycodone hydrochloride Rowex

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 label and the carton after "EXP". The expiry date refers to the last day of that month.

Do not store above 30°C.

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. Contents of the pack and other information

What Oxycodone hydrochloride Rowex contains

The active substance is oxycodone hydrochloride.

Oxycodone hydrochloride Rowex 5 mg Hard capsules

Each hard capsule contains 5 mg oxycodone hydrochloride, equivalent to 4.48 mg oxycodone.

Oxycodone hydrochloride Rowex 10 mg Hard capsules

Each hard capsule contains 10 mg oxycodone hydrochloride, equivalent to 8.96 mg oxycodone.

Oxycodone hydrochloride Rowex 20 mg Hard capsules

Each hard capsule contains 20 mg oxycodone hydrochloride, equivalent to 17.93 mg oxycodone.

The other ingredients are:

Content of capsule: microcrystalline cellulose, magnesium stearate

Capsule shell: gelatine, sodium laurilsulfate, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172), indigo carmine (E132),

Printing ink: shellac, iron oxide black (E172), potassium hydroxide (to adjust the pH).

What Oxycodone hydrochloride Rowex looks like and contents of the pack

Oxycodone hydrochloride Rowex 5 mg Hard capsules

Hard capsules of 14.4 mm in length with a dark pink body imprinted with "5" and a brown cap imprinted with "OXY".

Oxycodone hydrochloride Rowex 10 mg Hard capsules

Hard capsules of 14.4 mm in length with a white body imprinted with "10" and a brown cap imprinted with "OXY".

Oxycodone hydrochloride Rowex 20 mg Hard capsules

Hard capsules of 14.4 mm in length with a light pink body imprinted with "20" and a brown cap imprinted with "OXY".

Pack sizes:

Child-resistant perforated unit dose blisters: 20x1, 30x1, 50x1 and 100x1 hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Actavis ehf., Reykjavíkurvegur 78, IS-220 Hafnarfjörður, Iceland.

Balkanpharma Dupnitsa AD, 3 Samokovsko Shosse Str., Dupnitsa 2600, Bulgaria.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Lek Pharmaceuticals d.d., Verovškova ulica 57, Ljubljana, 1526, Slovenia.

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

Czech Republic	Dyxal
Germany:	Oxycodon-HCl HEXAL akut 5 mg Hartkapseln Oxycodon-HCl HEXAL akut 10 mg Hartkapseln Oxycodon-HCl HEXAL akut 20 mg Hartkapseln
Hungary:	Oxycodone Sandoz 5 mg kemény kapszula Oxycodone Sandoz 10 mg kemény kapszula Oxycodone Sandoz 20 mg kemény kapszula
Ireland:	Oxycodone hydrochloride Rowex 5 mg Hard capsules Oxycodone hydrochloride Rowex 10 mg Hard capsules Oxycodone hydrochloride Rowex 20 mg Hard capsules
Netherlands:	Oxycodon HCl Sandoz 5 mg, harde capsules Oxycodon HCl Sandoz 10 mg, harde capsules Oxycodon HCl Sandoz 20 mg, harde capsules
Poland:	Xanodal

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