

Oxycodone Actavis 5 mg capsules, hard Oxycodone Actavis 10 mg capsules, hard Oxycodone Actavis 20 mg capsules, hard 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

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1 What Oxycodone Actavis is and what it is used for

Oxycodone Actavis is a centrally acting, strong painkiller from the group of opioids.

Oxycodone Actavis is used to treat severe pain, which can only be adequately managed with opioid analgesics.

2 What you need to know before you take Oxycodone Actavis

Do not take Oxycodone Actavis

- 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, cor pulmonale (cardiac changes due to chronic overload of lung circulation) or acute, severe bronchial asthma.
- if you suffer from intestinal paralysis (paralytic ileus).
- if you have an acute abdomen or suffer from a delayed gastric emptying.
- if your doctor has ever told you not to take an opium based medicine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Oxycodone Actavis

- if you are older or debilitated.
- if your lung, liver or kidney function is severely impaired.
- if you suffer from myxoedema (certain illnesses of the thyroid gland), impaired function of the thyroid gland.
- if you suffer from adrenal insufficiency (Addison's disease).
- if you suffer from enlargement of the prostate (prostatic hypertrophy).
- if you suffer from alcoholism or are undergoing alcohol withdrawal.
- if you suffer from known opioid-dependence.
- if you suffer from inflammation of the pancreas (pancreatitis).
- in conditions with increased brain pressure such as head injury.
- if you suffer from disturbances of circulatory regulation.
- if you suffer from colic of the bile duct and ureter.
- if you suffer from low blood pressure or reduced blood volume.
- if you suffer from epilepsy or have a seizure tendency.
- if you take MAO inhibitors (for the treatment of depression).
- if you have recently undergone a bowel-surgery or abdominal surgery.
- if you suffer from an inflammatory bowel disorder.

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

Oxycodone Actavis has a primary dependence potential. When used for a long time tolerance to the effects may develop and progressively higher doses may be required to maintain pain control.

Chronic use of Oxycodone Actavis may lead to physical dependence and a withdrawal syndrome may occur upon abrupt cessation. When a patient no longer requires therapy with oxycodone hydrochloride, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal.

When used as directed in patients suffering from chronic pain the risk of developing physical or psychological dependence is markedly reduced and needs to be weighed against the potential benefit. Please discuss this with your doctor.

Increased sensitivity to pain that does not respond to dose increases can rarely develop. If this happens, your doctor will reduce your dose or switch you to an alternative opioid painkiller.

Oxycodone Actavis is not recommended for use before an operation or in the 24 hours after an operation.

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

Drinking alcohol whilst taking oxycodone Actavis 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 Actavis

Please refer to section 4 "Possible side effects" for information on counteractive measures which may be used to ease certain side effects.

Children and adolescents

Oxycodone Actavis has not been investigated in children under 12 years. Safety and efficacy have not been established and therefore use in children under 12 years of age is not recommended.

Elderly patients

In elderly patients without impairment of kidney and/or liver function a dose adjustment is usually not necessary.

Other medicines and Oxycodone Actavis

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

- Medicines that dampen the activity of the central nervous system, e.g.
 - sleeping pills or tranquilizers (sedatives, hypnotics)
 - other medicines that act on the nervous system (phenothiazines, neuroleptics)
 - medicines used to treat depression
 - muscle relaxants
 - medicines used to treat allergies or vomiting (antihistamines, antiemetics)
 - other opioids or alcohol can enhance the side effects of oxycodone, in particular depressed breathing (respiratory depression).
- Medicines with an anticholinergic effect, e.g.
 - other medicines that act against parasympathetic and cholinergic nerve fibres on the central nervous system (psychotropic medicines)
 - medicines used to treat allergies (antihistamines) or vomiting (antiemetics)
 - medicines used to treat Parkinson's disease can enhance certain side effects of oxycodone (e.g. constipation, dry mouth or urinary disturbances).
- Macrolide antibiotics (e.g. clarithromycin, erythromycin and telithromycin), some antifungal medicines (e.g. ketoconazole, voriconazole, itraconazole, and posaconazole) and antiviral medicines (e.g. boceprevir, ritonavir, indinavir, nelfinavir and saquinavir) can increase the effect of oxycodone and so the dose may need to be adjusted if you are taking these medicines.
- Cimetidine (a medicine used to treat heartburns), paroxetine (an antidepressant) and quinidine (to treat heart problems) can inhibit the metabolism of oxycodone and so increase its effects.
- Some antiepileptic medicines (carbamazepine, phenytoin), rifampicin (used to treat tuberculosis) and also the herbal remedy 'St John Wort' can increase decrease the effect of oxycodone
- Monoamine oxidase inhibitors (a medicine used to treat depression) can enhance the side effects of oxycodone (e.g. excitation, decrease or increase in blood pressure).
- In individuals a clinically relevant increase or decrease of blood clotting have been observed if anticoagulants of the coumarin type (medicines against blood clotting) are co-applied with oxycodone hydrochloride.

Oxycodone Actavis with food, drink and alcohol

Oxycodone Actavis may be taken with or without food with a sufficient amount of liquid.

Alcohol enhances the impairment of alertness and reactivity and may enhance potential side effects such as drowsiness and depressed breathing.

Grapefruit juice can inhibit the metabolism of oxycodone which will increase its effect. Therefore you should avoid drinking grapefruit juice while taking Oxycodone Actavis.

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 avoid Oxycodone Actavis during pregnancy if possible. 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. Use of oxycodone during childbirth can cause breathing problems in the newborn.

Breast-feeding

You should not use Oxycodone Actavis when you are breast-feeding as oxycodone passes into breast milk and may cause breathing problems in the newborn.

Driving and using machines

Oxycodone impairs alertness and reactivity to such an extent that the ability to drive and operate machinery is affected or ceases altogether. To look at the possible side effects affecting the motor skills and concentration see section 4 "Possible side effects". With stable therapy, a general ban on driving a vehicle may not be necessary. The treating physician must assess the individual situation. Please discuss with your doctor whether or under what conditions you can drive a vehicle.

3 How to take Oxycodone Actavis

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

Adults and adolescents over 12 years

The usual starting dose is one 5 mg capsule every 6 hours. However, your doctor will prescribe the appropriate dose and frequency of administration required to treat your pain.

If you find that you are still in pain whilst taking these capsules discuss this with your doctor.

Method of use

Oxycodone Actavis capsules should be swallowed whole with a sufficient amount of liquid.

Oxycodone Actavis should not be taken with alcoholic beverages.

You must only take the capsules by mouth. The capsules contents should never be injected as this may lead to serious side effects, which may be fatal.

Adults with renal or liver impairment

The usual starting dose is half the recommended dose for adults. Your doctor will prescribe the appropriate dose based on your clinical situation and by using a more suitable formulation if available.

Use in children

Oxycodone Actavis is not recommended for children under 12 years of age.

If you take more Oxycodone Actavis than you should

If you have taken more Oxycodone Actavis than prescribed you should inform your doctor or your local poison control center immediately. The following symptoms may occur: constricted pupils, depressed breathing, muscle weakness, drowsiness and drop in blood pressure. In severe cases circulatory collapse, mental and motor inactivity, unconsciousness, slowing of the heart rate and accumulation of water in the lungs may occur; abuse of high doses of strong opioids such as oxycodone can be fatal. In no case should you expose yourself to situations requiring elevated concentration e.g. driving a car.

If you forget to take Oxycodone Actavis

If you miss a dose you should take the next dose as soon as you remember and then carry on as before. Do not take two doses within 4 hours. Do not take a double dose to make up for forgotten capsules.

If you stop taking Oxycodone Actavis

Do not stop treatment without informing your doctor.

When a patient no longer requires therapy with Oxycodone Actavis, 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.

Significant side effects or signs to consider and measures to be taken when these side effects or signs occur:

If you experience any of the following side effects, stop taking Oxycodone Actavis and contact your doctor immediately. Depressed breathing is the most significant risk induced by opioids and is most likely to occur in elderly or debilitated patients. As a consequence, in predisposed patients opioids can cause severe drops in blood pressure. Apart from this oxycodone can cause constricted pupils, bronchial spasms and spasms in smooth muscles and suppress the cough reflex.

Other possible side effects

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

- sedation (tiredness to drowsiness)
- dizziness
- headache
- constipation
- feeling sick
- vomiting
- itching

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

- loss of appetite
- several psychological side effects such as
 - changes in mood (e.g. generalised fear, depression)
 - changes in activity (mostly sedation, sometimes accompanied by tiredness, occasionally increase with nervousness and sleep disorders)
 - changes in performance (thought process disorder, confusion)
- trembling (tremor)
- wheezing, shortness of breath, hiccups
- dry mouth, stomach pain, diarrhoea, indigestion (dyspepsia)
- rash, increased sweating
- increased urge to urinate
- feeling weak (asthenia)

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

- allergic reactions
- abnormal production of antidiuretic hormone
- lack of water in the body (dehydration)
- change in perception such as depersonalisation and seeing, hearing or feeling things that are not there (hallucinations), decreased sexual drive, restlessness, extreme emotional behaviour, a feeling of extreme happiness, drug dependence (see section 2)
- increased or decreased muscle tone, coordination disturbances, involuntary muscle contractions, fits; in particular in patients suffering from epilepsy or with a tendency to fits, increased tightness and difficulty in stretching muscles, speech disorders, fainting, tingling or pins and needles (paraesthesia), reduced sense of touch (hypoesthesia), migraine, change in taste, loss of memory
- changes in tear secretion, constriction of the pupil, visual impairment
- abnormally acute sense of hearing (hyperacusis), feeling of dizziness or spinning (vertigo)
- accelerated heart rate, being aware of the heart beat
- widening of the blood vessels (vasodilatation)
- difficulty in breathing, cough, sore throat, runny nose, voice changes
- difficulty swallowing, mouth ulcers, inflammation of the gums, inflamed mouth (stomatitis), wind, belching, intestinal obstruction (ileus)
- increased liver enzymes
- dry skin
- difficulty in passing urine
- impotence
- pain (e.g. chest pain), chills, excessive fluid in the tissues (oedema), feeling unwell, physical dependence with withdrawal symptoms, drug tolerance requiring increased dosage to maintain effect, thirst
- injuries due to accidents

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

- herpes simplex (disorder of the skin and mucosa)
- lymph node disease (lymphadenopathy)
- increased appetite

- lowering of blood pressure, dizziness when standing up from a sitting or lying position
- gum bleeding, tarry stools, tooth staining and damage
- itchy skin rash (hives), increased sensitivity to light (photosensitivity)
- muscle spasms
- blood in the urine (haematuria)
- changes in body weight (loss or rise), cellulitis

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

- scaly rash (exfoliative dermatitis)

Unknown frequency (cannot be estimated from the available data)

- severe hypersensitivity reactions (anaphylactic reactions)
- aggression
- increased sensitivity to pain which cannot be improved by increasing the dose
- tooth decay
- pain on the right side of the abdomen, itchiness and jaundice caused by inflammation of the gall bladder
- absence of menstrual periods (amenorrhoea)

Counteractive measures:

If you observe any of the above listed side effects your doctor usually will take appropriate measures. The side effect constipation may be prevented by fiber enriched diet and increased intake of fluids. If you are suffering from sickness or vomiting your doctor will prescribe you an appropriate medicine.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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

5 How to store Oxycodone Actavis

Keep this medicine out of the sight and reach of children.

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

Do not store above 30°C.

For HDPE container only:

Use within 6 months after opening.

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 Actavis contains

- The active substance is oxycodone hydrochloride.
Oxycodone Actavis 5 mg: Each capsule contains 5 mg oxycodone hydrochloride.
Oxycodone Actavis 10 mg: Each capsule contains 10 mg oxycodone hydrochloride.
Oxycodone Actavis 20 mg: Each capsule contains 20 mg oxycodone hydrochloride
- The other ingredients are:
Capsule content: microcrystalline cellulose, magnesium stearate.
Capsule shell: Gelatine, sodium laurilsulfate, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172), indigotine (E132). *Printing ink:* shellac, iron oxide black (E172), potassium hydroxide.

What Oxycodone Actavis looks like and contents of the pack

Oxycodone Actavis 5 mg:

Hard capsules, 14.4 mm in length, with a dark pink body marked with '5' and a brown cap marked with 'OXY'.

Oxycodone Actavis 10 mg:

Hard capsules, 14.4 mm in length, with a white body marked with '10' and a brown cap marked with 'OXY'.

Oxycodone Actavis 20 mg:

Hard capsules, 14.4 mm in length, with a light pink body marked with '20' and a brown cap marked with 'OXY'.

Pack sizes:

Blisters: 10, 14, 20, 28, 30, 50, 56, 90, 98 and 100 capsules

Child resistant blisters : 10, 14, 20, 28, 30, 50, 56, 90, 98 and 100 capsules

Child resistant capsule container: 56, 98, 100 and 250 capsules

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Actavis Group PTC ehf
Reykjavíkurvegur 76-78
220 Hafnarfjörður
Iceland

Manufacturer

Actavis Group PTC ehf
Reykjavíkurvegur 76-78
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This medicinal product is authorised in the Member States of the EEA under the following names:

SE	Oxikodon Actavis
DE	Oxycodonhydrochlorid Puren 5 mg, 10 mg, 20 mg Hartkapseln
DK	Oxycodon Actavis
FI	Oxycodon Actavis 5 mg kapseli, kova Oxycodon Actavis 10 mg kapseli, kova Oxycodon Actavis 20 mg kapseli, kova
IE	Oxycodone Actavis 5 mg, 10 mg, 20 mg Capsules, hard
NL	Oxycodon HCl Aurobindo 5 mg, 10 mg, 20 mg, capsules hard
NO	Oxycodone Actavis
UK	Lynlor 5mg, 10mg and 20mg Capsules, hard
BG	Oxycodone Actavis

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