

Package leaflet: Information for the patient

Oxikodon Actavis 5 mg capsules, hard
Oxikodon Actavis 10 mg capsules, hard
Oxikodon 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

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

1. What Oxikodon Actavis is and what it is used for

Oxikodon Actavis contains the active substance oxycodone hydrochloride. It is a strong painkiller that belongs to a group of medicines called opioids.

Oxikodon Actavis is used in adults and adolescents (from 12 years and older) for the treatment of severe pain, which can be adequately managed only with opioid analgesics.

2. What you need to know before you take Oxikodon Actavis

Do not take Oxikodon Actavis

- if you are allergic to oxycodone hydrochloride or any of the other ingredients of this medicine (listed in section 6),
- if you have severe breathing problems (respiratory depression) with too little oxygen in the blood (hypoxia) and/or too much carbon dioxide in the blood (hypercapnia),
- if you suffer from a severe, chronic lung disease, which is accompanied by an obstruction of the airways (severe chronic obstructive pulmonary disease, also called COPD),
- if you were diagnosed with cor pulmonale (a change in the heart after long-term lung disease),
- if you suffer from severe bronchial asthma,
- if you have a condition where the bowel stops working (paralytic ileus),
- if you have a syndrome with acute severe abdominal pain called 'acute abdomen' or suffer from a delayed gastric emptying,
- if your doctor has told you not to take strong pain killers (opioids).

Warnings and precautions

Talk to your doctor or pharmacist before taking Oxikodon Actavis

- if you are older or debilitated,
- if you have severe lung problems,

- if you have repeated pauses in breathing when you sleep (sleep apnoea), as this condition may worsen,
- if your liver or kidney function is impaired,
- if you suffer from myxoedema (certain illnesses of the thyroid gland) or impaired function of the thyroid gland,
- if you have poor adrenal gland function (your adrenal gland is not working properly) for example Addison's disease,
- if you have a mental illness due to intoxication with alcohol or other substances (toxic psychosis),
- if you suffer from alcoholism,
- if you have alcohol or drug related withdrawal symptoms (e.g. delirium tremens),
- if you have an enlargement of the prostate (prostatic hypertrophy),
- if you suffer from inflammation of the pancreas (pancreatitis) which may cause severe pain in your abdomen or back,
- if you have diseases of the biliary tract, colic of the bile duct and ureter,
- if you suffer from obstructive or inflammatory bowel diseases,
- if you suffer from constipation,
- in conditions with increased brain pressure such as head injury,
- if you suffer from epilepsy or have a seizure tendency,
- if you take monoamine oxidase inhibitors, also referred to as MAO inhibitors (for the treatment of depression) or you have taken them in the last two weeks (see section 2 'Other medicines and Oxikodon Actavis'),
- if you have recently had bowel or abdominal surgery,
- if your doctor suspects that your bowel does not work properly,
- if you have low blood pressure or reduced blood volume.

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

Shallow and slowed down breathing (respiratory depression)

The main hazard of an opioid overdose is shallow and slowed down breathing (respiratory depression). This occurs predominantly in elderly and debilitated patients and may also cause blood oxygen levels to fall. This could cause fainting for example.

Sleep-related breathing disorders

Oxikodon Actavis 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.

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 Oxikodon Actavis 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 Oxikodon Actavis 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 Oxikodon Actavis, 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 Oxikodon Actavis').

Withdrawal symptoms

If treatment is stopped abruptly withdrawal symptoms may occur which may include yawning, dilation of the pupil of the eye, tear disorder, runny nose, shaking (tremors), sweating, anxiety, restlessness, seizures or difficulty in sleeping. When therapy with Oxikodon Actavis is no longer necessary, your doctor will reduce your daily dose gradually to avoid this happening.

Treatment of chronic pain not related to cancer

Opioids are not the first choice of treatment for pain not related to cancer and are not recommended as the only treatment. Opioids should be used as part of a comprehensive treatment program involving other medications and treatment modalities. Your doctor should monitor you closely and make necessary adjustments to your dose while you are taking Oxikodon Actavis to prevent addiction and abuse.

Inflammation of the pancreas and the biliary tract system

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.

Increased sensitivity to pain

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

Abusive injection

Oxikodon Actavis capsules are for oral use only. In case of abusive injection (injection in a vein) the capsule content may lead to serious, potentially fatal events.

Operations

Oxikodon Actavis is not recommended for use before an operation or in the 24 hours after an operation. If you are going to have an operation, make sure you tell your doctors that you are taking Oxikodon Actavis.

Hormonal changes

Similar to other opioids, Oxikodon Actavis may affect the normal production of hormones in the body such as cortisol or sex hormones. Symptoms may be feeling or being sick, loss of appetite, tiredness,

dizziness or disturbances of sexual function, changes in menstrual bleeding or impotence. Please discuss this with your doctor.

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

Children below 12 years of age

Safety and efficacy of Oxikodon Actavis have not been tested sufficiently in children under 12 years of age. Therefore, treatment with Oxikodon Actavis is not recommended in children under 12 years of age.

Other medicines and Oxikodon Actavis

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

Concomitant use of opioids including Oxikodon Actavis 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 Oxikodon Actavis together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

The side effects of Oxikodon Actavis can be more frequent or severe, if you use Oxikodon Actavis simultaneously with medicines which may affect brain function. Examples of side effects that may occur are shallow and slowed down breathing (respiratory depression).

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 these capsules with some other medicines, the effect of these capsules or the other medicine may be changed, furthermore the risk of side effects may be increased. Tell your doctor or pharmacist if you are taking:

- a type of medicine known as a monoamine oxidase inhibitor (such as tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid) or you have taken this type of medicine in the last two weeks (see 'Warnings and precautions'),
- medicines to help you sleep or stay calm (for example anti-anxiety medication, hypnotics or sedatives, including benzodiazepines),
- medicines to treat depression (such as paroxetine or fluoxetine),
- medicines to treat allergies, travel diseases or vomiting (antihistamines, antiemetics),
- medicines to treat psychiatric or mental disorders (such as antipsychotics, phenothiazines or neuroleptic drugs),
- medicines to treat epilepsy, pain, and anxiety such as gabapentin and pregabalin,
- medicines called muscle relaxants to relieve muscle cramps,
- medicines to treat Parkinson's disease,
- other strong painkillers (opioids),
- cimetidine (a medicine for stomach ulcers, indigestion or heartburn),
- medicines to treat fungal infections (such as ketoconazole, voriconazole, itraconazole, or posaconazole),

- medicines to treat bacterial infections (such as clarithromycin, erythromycin or telithromycin),
- a specific type of medicine known as a protease inhibitor to treat HIV (examples include boceprevir, ritonavir, indinavir, nelfinavir or saquinavir),
- rifampicin to treat tuberculosis,
- carbamazepine (a medicine to treat seizures, fits or convulsions and certain pain conditions),
- phenytoin (a medicine to treat seizures, fits or convulsions),
- a herbal remedy called St John's Wort (also known as Hypericum perforatum),
- quinidine (a medicine to treat an irregular heartbeat),
- medicines called coumarins to prevent your blood clotting or to help thin your blood (blood thinners).

Also, tell your doctor if you have recently been given an anaesthetic.

Oxikodon Actavis with food, drink and alcohol

Grapefruit juice

Grapefruit juice can increase the effect of oxycodone. Therefore, you should avoid drinking grapefruit juice while taking Oxikodon Actavis.

Alcohol

Drinking alcohol whilst taking Oxikodon Actavis may make you feel more sleepy or drowsy or increase the risk of serious side effects such as shallow and slow breathing with a risk of stopping breathing, and loss of consciousness. It is recommended not to drink alcohol while you are taking Oxikodon 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

If possible, use of this product in pregnant women should be avoided. There are limited data from the use of oxycodone in pregnant women.

Oxycodone crosses the placenta into the blood circulation of the baby. Use of oxycodone during pregnancy can cause withdrawal symptoms in newborns. Infants born to mothers who have received oxycodone during the last 3 to 4 weeks before giving birth should be monitored for respiratory depression. Use of oxycodone during childbirth can cause breathing problems in the newborn.

Oxikodon Actavis should only be used during pregnancy if the benefit outweighs the possible risks for the baby.

Breast-feeding

You should not take Oxikodon Actavis if you are breast-feeding, as oxycodone may pass into breast milk and may cause shallow and slowed down breathing (respiratory depression) in the breast-fed child.

Driving and using machines

Oxycodone may impair your ability to drive or use machines.

This is particularly likely at the start of treatment with Oxikodon Actavis, after a dose increase or changes in your medicinal product therapy and if Oxikodon Actavis is combined with medicines, which may affect brain function.

With stable therapy, a general ban on driving a vehicle is not necessary. The treating physician must assess the individual situation. Please discuss with your doctor whether or not, or under which conditions you may drive or use machines.

Oxikodon Actavis 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 Oxikodon Actavis

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 Oxikodon Actavis, 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 Oxikodon Actavis').

Adults and adolescents (from 12 years and older)

The recommended starting dose is 5 mg oxycodone hydrochloride every 6 hours. The time between doses can be reduced to 4 hours if necessary. Oxikodon Actavis should not be taken more than 6 times a day.

Your doctor adjusts the dose individually for you and prescribes the dose needed to treat the pain. If you find that you are still in pain whilst taking these capsules discuss this with your doctor. Do not change the dose under any circumstances without checking with your doctor.

The daily dose and any dose adjustments during treatment are determined by the treating physician and depend on the previous dosage. Patients who have already taken opioids can start treatment with higher dosages taking into account their experience with opioid treatment.

Elderly patients

If kidney or liver function is not impaired, a dose adjustment is usually not necessary for elderly patients.

Patients with liver or kidney problems or with a low body weight

The recommended 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.

Duration of treatment

Your doctor will tell you how long you should take Oxikodon Actavis.

Do not stop taking Oxikodon Actavis without consulting your doctor (see 'If you stop taking Oxikodon Actavis').

Method of use

Oxikodon Actavis capsules should be swallowed whole with a sufficient amount of liquid and may be taken with or without food.

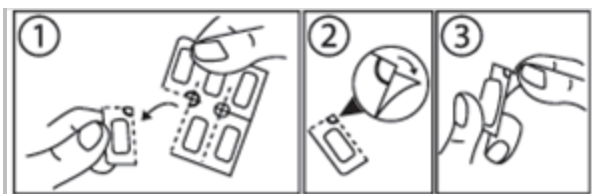
Oxikodon Actavis should not be taken with alcoholic beverages (see section 2, 'Oxikodon Actavis with food, drink and alcohol').

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.

[For child resistant peel-off blisters only:]

Instructions for use of child resistant peel-off blisters:

1. Do not push the capsule directly out of the pocket
2. Separate one blister cell from the strip at the perforations (see 1)
3. Carefully peel off the backing to open the pocket (see 2 and 3)



If you take more Oxikodon Actavis than you should

If you have taken more Oxikodon Actavis than prescribed or someone accidentally swallows your capsules, you should inform your doctor or your local poison control center immediately.

An overdose may result in:

- constricted pupils (miosis),
- shallow and slowed down breathing (respiratory depression),
- drowsiness,
- decreased tension of skeletal muscles,
- drop in blood pressure,
- a brain disorder (known as toxic leukoencephalopathy).

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 Oxikodon 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 Oxikodon Actavis

Do not stop treatment without consulting your doctor.

If you stop taking Oxikodon Actavis, you may experience withdrawal symptoms (e.g. yawning, dilation of the pupil of the eye, tear disorder, runny nose, shaking (tremors), sweating, anxiety, restlessness, seizures or difficulty in sleeping). Therefore, it may be advisable that your doctor gradually reduces 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.

If you experience any of the following side effects, stop taking Oxikodon Actavis and contact a doctor or go to the nearest emergency department immediately:

- sudden difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body – these are signs of severe allergic reactions (frequency is not known: cannot be estimated from the available data)
- shallow and slowed down breathing – this occurs predominantly if you are elderly or debilitated and is the main hazard if you have taken too much medicine (uncommon side effect, may affect up to 1 in 100 people)
- a drop in blood pressure – you may feel dizzy and faint if this happens (rare side effect, may affect up to 1 in 1,000 people)
- reduction in size of the pupils in the eye (uncommon side effect, may affect up to 1 in 100 people)

- cramping of the bronchial muscles (causing shortness of breath) and reduced ability to cough when you need to (common side effect, may affect up to 1 in 10 people)

Other possible side effects

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

- feel more sleepy than normal
- dizziness, headache
- constipation, feeling sick (nausea), being sick (vomiting)
- itching.

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

- decreased appetite
- anxiety, confusion, depression, nervousness, difficulty sleeping, abnormal thinking
- involuntary trembling or shaking, feeling lethargic
- shortness of breath, difficulty in breathing or wheezing (dyspnoea)
- abdominal pain, diarrhoea, dry mouth, indigestion
- skin reactions/rash, excessive sweating
- increased urge to urinate
- feeling weak (asthenia), feeling exhausted (fatigue).

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

- hypersensitivity
- abnormal production of antidiuretic hormone
- lack of water in the body (dehydration)
- agitation, mood swings, a feeling of extreme happiness, perception disturbances (e.g. hallucination, derealisation)
- decreased sexual drive
- drug dependence (see also section 2 'Warnings and precautions')
- unusual muscle stiffness, decreased muscle tone, involuntary muscle contractions
- seizures (in particular in patients suffering from epilepsy or with a tendency to seizures)
- reduced sensitivity to pain or touch (hypoesthesia), speech disorders, fainting, tingling or pins and needles (paraesthesia), coordination disturbances, change in taste
- loss of memory, migraine
- changes in tear secretion, vision disorder
- increased sensitivity to sound (hyperacusis), feeling of dizziness or spinning (vertigo)
- accelerated pulse, sensation of irregular and forceful heartbeat (in the context of withdrawal syndrome)
- widening of the blood vessels (vasodilatation)
- voice changes, cough, pharyngitis, runny nose
- oral ulcers, inflammation of the gums, inflamed mouth (stomatitis), difficulty swallowing, flatulence, belching, intestinal obstruction (ileus)
- increased liver enzymes, ureteral spasm
- dry skin
- difficulty in passing urine
- impotence, reduced levels of sex hormones
- chills, generally feeling unwell, thirst
- excessive fluid in the tissues (oedema), swelling of the hands, ankles or feet
- physical dependence with withdrawal symptoms, pain (e.g. chest pain)
- a need to take increasingly higher doses of Oxikodon Actavis to gain the same level of pain relief (drug tolerance)
- 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
- dark colored tarry stools, tooth discolouration, gum bleeding
- hives (urticaria), increased sensitivity to light (photosensitivity)
- blood in 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).

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

- aggression
- increased sensitivity to pain which cannot be improved by increasing the dose
- sleep apnoea (breathing pauses during sleep)
- tooth decay
- pain on the right side of the abdomen, itchiness and jaundice caused by inflammation of the gall bladder
- a problem affecting a valve in the intestines that may cause severe upper abdominal pain (sphincter of Oddi dysfunction)
- absence of menstrual periods (amenorrhoea)
- long term use of Oxikodon Actavis 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.

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 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 Oxikodon Actavis

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 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 Oxikodon Actavis contains

- The active substance is oxycodone hydrochloride.
Oxikodon Actavis 5 mg: Each capsule contains 5 mg oxycodone hydrochloride corresponding to 4.48 mg oxycodone.
Oxikodon Actavis 10 mg: Each capsule contains 10 mg oxycodone hydrochloride corresponding to 8.96 mg oxycodone.
Oxikodon Actavis 20 mg: Each capsule contains 20 mg oxycodone hydrochloride corresponding to 17.93 mg oxycodone.
- 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 Oxikodon Actavis looks like and contents of the pack

Oxikodon 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'.

Oxikodon Actavis 10 mg:

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

Oxikodon 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:

Push-through blisters: 10, 14, 20, 28, 30, 50, 56, 90, 98 and 100 capsules

Child resistant peel-off 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 and Manufacturer

[To be completed nationally]

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

[To be completed nationally]

This leaflet was last revised in

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