

Package leaflet: Information for the patient

Oxycodone G.L. 10 mg/ml oral solution

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

1. What <Product name> is and what it is used for

<Product name> contains the active substance oxycodone hydrochloride which belongs to a group of medicines called opioids and has a strong analgesic (painkilling) effect.

<Product name> is indicated 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 <Product name>

Do not take <Product name>

- if you are allergic to oxycodone hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- if you have breathing problems, such as breathing more slowly or more weakly than expected (respiratory depression), low amount of oxygen or too much carbon dioxide in your blood.
- if you have a severe chronic lung disease associated with narrowing of the airways (COPD = chronic obstructive pulmonary disease).
- if you have a certain heart condition after long-term lung disease known as cor pulmonale.
- if you have severe bronchial asthma.
- if you have a type of bowel obstruction called paralytic ileus.
- if you have acute severe stomach pain or your stomach empties more slowly than it should (delayed gastric emptying).

Warnings and precautions

Talk to your doctor or pharmacist before using <Product name>

- if you are elderly or debilitated (weak).
- if your lung, liver or kidney function is impaired.
- if you have an impaired function of the thyroid gland (hypothyroidism or myxoedema).
- if you have poor adrenal gland function (your adrenal gland is not working properly) for example Addison's disease.
- if you have a mental disorder as a result of intoxication with another substance or alcohol.

- if you have delirium tremens due to alcohol withdrawal causing severe confusion, hallucinations and shaking.
- if you have enlargement of the prostate.
- if you have an inflammation of the pancreas (pancreatitis).
- if you have problems with your gall bladder or urinary tract, including difficulty or pain passing urine.
- if your doctor suspects you have intestinal paralysis (a condition where the bowel has stopped working)
- if you have inflammatory bowel disease.
- if your brain pressure is increased e.g. as a result of a head injury.
- if you have impaired consciousness
- if you have low blood pressure or if you have a reduced blood volume.
- if you are also taking a type of medicine known as MAO inhibitors (generally used to for the treatment of depression or Parkinson's disease) or if you have been taking them within the last 2 weeks (see "Other medicines" below).

The most severe risk of opioid overdose is very slow or weak breathing (respiratory depression), which is most common in the elderly or frail patients. Opioids may also cause a sudden, severe drop in blood pressure in people with an increased risk of this phenomenon. This may lead to fainting, for example.

Sleep-related breathing disorders

<Product name> 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.

When <Product name> is used for long-time treatment, **tolerance** to the medicine may occur. This means, that you may need a higher dose to achieve the desired pain relief. Do not change the dosage without consulting your doctor.

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 <Product name> 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 <Product name> 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 <Product name>, 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 <Product name>).

<Product name> has a **dependence potential**. If the treatment is stopped too suddenly, withdrawal symptoms such as yawning, dilated pupils, tearing, runny nose, tremors, sweating, chills, anxiety, restlessness, feeling your heartbeat or muscle pain may occur. Other symptoms also may develop, including irritability, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, loss of appetite, vomiting, diarrhoea, or increased blood pressure, respiratory rate or heart rate.

If you no longer need treatment, your doctor will gradually reduce your daily dose. Your doctor will weigh the possible risks against the expected and needs to be evaluated in relation to the benefit. Ask your doctor if you have any questions about this.

The active ingredient oxycodone hydrochloride, like other highly effective opioids (strong pain killers), has **potential for abuse**. The development of psychological addiction is possible. <Product name> should only be used with particular caution if there has been or has been a history of alcohol, drug or drug abuse.

Particularly in high doses, **increased sensitivity to pain** (hyperalgesia) can occur, which does not respond to a further increase in the dose of <Product name>. Your doctor will then decide whether to reduce the dose or switch to another strong pain reliever (opioid).

If you **need to have an operation**, please tell your doctor that you are taking <Product name>.

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**.

Similar to other opioids, oxycodone can affect the body's **normal production of hormones** (such as **cortisol and sex hormones**). Symptoms may be severe abdominal pain, nausea and vomiting, low blood pressure, extreme fatigue, lack of appetite and weight loss. If you have these symptoms, contact your doctor, who will decide if you need to take hormone supplement.

Other medicines and <Product name>

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

Concomitant use of <Product name> 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 <Product name> 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.

The risk of side effects is increased if <Product name> is used at the same time as medicines that can affect brain function.

Medicines that affect the way the brain works include:

- sleeping pills or sedatives (e.g. hypnotics or sedatives, including benzodiazepines)
- medicines for depression (e.g. paroxetine or amitriptyline), including those belonging to a group of MAOIs (please also see Section "Warnings and precautions"),
- medicines for allergies, motion sickness or vomiting (antihistamines, antiemetics),
- medicines for psychological or mental disorders (such as psychotropic drugs, phenothiazines or neuroleptics),
- Medicines used to treat epilepsy, pain and anxiety such as e.g. gabapentin and pregabalin.

Please tell your doctor or pharmacist if you are taking any of the medicines from the following list:

- muscle relaxants used to treat muscle spasms
- medicines used to treat Parkinson's disease,
- other strong pain relievers (opioids),
- cimetidine (a medicine for stomach ulcers, indigestion or heartburn),
- medicines for fungal infections (such as ketoconazole, voriconazole, itraconazole or posaconazole),
- medicines for bacterial infections (such as clarithromycin, erythromycin or telithromycin),
- medicines from the group of protease inhibitors to treat HIV infection (e.g. boceprevir, ritonavir, indinavir, nelfinavir or saquinavir),
- rifampicin for tuberculosis,
- carbamazepine (a medicine for epilepsy or seizures and for certain types of pain),
- phenytoin (a medicine for epilepsy or seizures),
- the medicinal plant St. John's wort (also known as Hypericum perforatum),
- quinidine (a medicine for irregular heartbeat),
- certain medicines to prevent blood clotting or to thin the blood (such as coumarin medicines).

<Product name> with drink and alcohol

<Product name> should not be taken with alcohol. Alcohol use could increase serious side-effects of oxycodone, such as sleepiness and drowsiness and slow and shallow breathing.

Grapefruit juice may increase the levels of <Product name> in your blood. Check with your doctor if you drink grapefruit juice regularly.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

The use of <Product name> should be avoided to the extent possible during pregnancy.

Prolonged use of oxycodone during pregnancy can cause withdrawal symptoms in newborns. If oxycodone is given during childbirth it may cause breathing difficulties (respiratory depression) in the newborn.

Breast-feeding

Do not take this medicine if you are breast-feeding. Oxycodone passes into breast milk and may cause shallow and slow breathing (respiratory depression) in the breast-fed child.

Driving and using machines

<Product name>

may impair the ability to drive and use machines. This is to be expected especially at the beginning of therapy with <Product name>, after increasing the dose or after switching preparation, as well as when <Product name> interacts with alcohol or drugs that can impair brain function. In the case of stable therapy, a general driving ban is not necessary. Your attending physician must assess your individual situation.

<Product name> 10 mg/ml oral solution contains Sunset yellow FCF (E 110)

<Product name> 10 mg/ml oral solution contains the colouring agent Sunset yellow FCF (E 110) which may cause allergic reactions.

<Product name> 10 mg/ml oral solution contains sodium

This medicine contains 4.5 mg sodium (main component of cooking/table salt) in each ml. This is equivalent to 0.2% of the recommended maximum daily dietary intake of sodium for an adult.

<Product name> 1 mg/ml oral solution contains sodium benzoate (E211)

This medicine contains 1 mg sodium benzoate (E211) in 10 mg/ml oral solution.

3. How to take <Product name>

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 <Product name>, 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 <Product name>).

Do not change the dosage without consulting your doctor.

You should be given the lowest effective dose sufficient to relieve your pain.

If you have previously been treated with opioids, your doctor may start your therapy with a higher dose. It may be necessary to increase the dose gradually if the pain relief is insufficient or if the pain becomes worse.

Adults and adolescents (from 12 years and older)

Your doctor will adjust your dosage according to pain intensity and to your individual needs.

Use the oral syringe provided in the carton box.

The usual starting dose is 0.5 ml of the oral solution every 6 hours. This is equivalent to 5 mg oxycodone hydrochloride.

Your doctor will decide how much you should take every day after the dose initiation, and how to divide your total daily dose into morning and evening doses. Your doctor will also advise you on any dose adjustments that may become necessary during treatment.

If needed to treat your pain, your doctor may instruct you to take the doses every 4 hours. However, <Product name> should not be taken more often than 6 times a day.

If you experience pain between doses of <Product name> you may require higher doses of <Product name>. Please talk to your doctor if you have this problem.

<Product name> should not be taken longer than necessary. If you require long-term treatment of severe pain you will be switched to an alternative dosage form of oxycodone.

Elderly (65 years and older)

Elderly patients should be treated with caution using the lowest dose possible to receive pain control.

Patients with kidney and/or liver impairment

Your doctor may prescribe a lower starting dose.

Other risk patients:

If you are light or if your body metabolizes medicines more slowly, your doctor may prescribe a lower starting dose.

Use in children (below 12 years):

Safety and efficacy of <Product name> have not been tested sufficiently in children under 12 years of age. Therefore, treatment with <Product name> is not recommended in children under 12 years of age.

Method of administration

- The solution should be swallowed.
- Use the oral syringe provided in the carton box.
- There are two ways in which you can choose to drink the medicine. For more information please see below mentioned instructions for use. You can take this medicine with or without food.

Instructions for use

Your doctor will show you how to use the oral syringe, before you use it for the first time. If you have any questions, please contact your doctor or pharmacist.

Open the bottle by pressing the cap while turning it anti-clockwise (figure 1).



Figure 1

Follow these steps each time you take <Product name>:

- o Put the oral syringe into the adaptor opening (figure 2).
- o Turn the bottle upside down (figure 3).

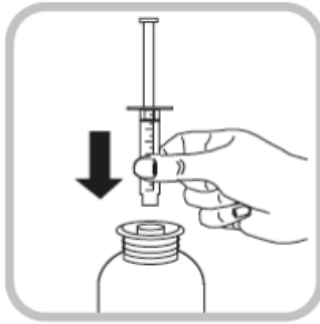


Figure 2

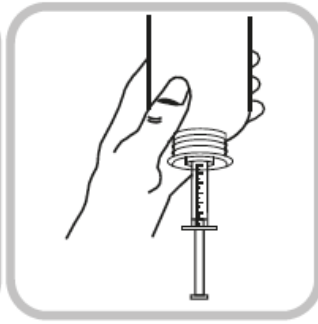


Figure 3

- o Hold the bottle upside down in one hand and use the other hand to fill the oral syringe.
- o Pull the piston down to fill the oral syringe with a small amount of solution (figure 4).
- o Push the piston up to get rid of any bubbles (figure 5).
- o Pull the piston down to the millilitre (ml) dose marker prescribed by your doctor (figure 6).

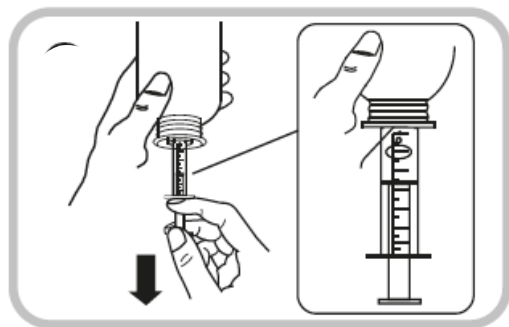


Figure 4

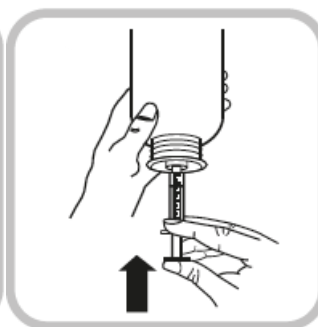


Figure 5

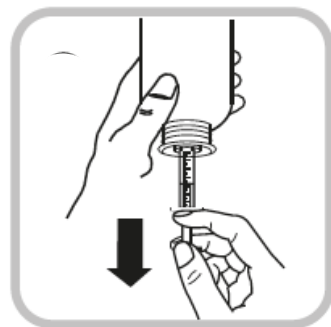


Figure 6

- o Turn the bottle the right way up (figure 7).
- o Take the oral syringe out of the adaptor (figure 8).

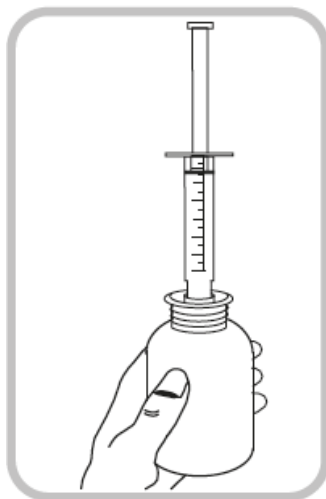


Figure 7



Figure 8

There are two ways in which you can choose to drink the medicine:

- o Empty the contents of the oral syringe into a little water by pushing the piston to the bottom of the oral syringe (figure 9) – you will then need to drink all of the water (add just enough to make it easy to drink) or
- o Drink the solution directly from the oral syringe without water (figure 10).

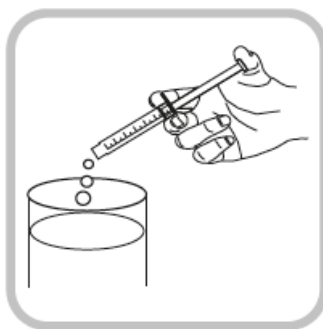


Figure 9



Figure 10

- o Close the bottle with the plastic screw cap (you do not need to remove the adaptor).
- o Wash the oral syringe with water only (figure 11).



Figure 11

If you take more <Product name> than you should

If you have taken more <Product name> than you should or someone else has taken it by mistake, immediately contact a doctor, hospital or your local poison control center (<phone number>).

Overdosing can cause:

- constriction of the pupils,
- very slow or weak breathing (respiratory depression),
- drowsiness up to absent-mindedness (narcosis-like state),
- decreased tension in the skeletal muscles,
- slowing your pulse,
- drop in blood pressure
- a brain disorder (known as toxic leukoencephalopathy).

In more severe cases, unconsciousness (coma), water retention in the lungs and circulatory failure can occur. Abuse of high doses of strong opioids such as oxycodone can be fatal.

If you forget to take <Product name>

If you take a smaller dose of <Product name> than prescribed, or if you miss a dose, adequate pain relief will probably not be achieved.

If you forget to take one dose, you can take the forgotten dose as soon as you remember it. You should always leave 4-6 hours between your doses (as directed by your doctor).

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

If you stop taking <Product name>

Do not stop treatment without first speaking with your doctor.

If you stop taking <Product name>, 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 the following symptom occurs:

- **Very slow or weak breathing** (respiratory depression). This is the most most serious risk in connection with medicines such as <Product name> (opioids), and may even be fatal after high doses of this medicine.

Other side effects that may occur:

Very common: may affect more than 1 in 10 people

- Sleepiness to drowsiness, dizziness, headache
- Constipation, feeling or being sick. Your doctor will prescribe an appropriate medicine to treat these symptoms.
- Itching

Common: may affect up to 1 in 10 people

- Changes in mood (anxiety, confusion, depression, nervousness, sleep disorders, abnormal thoughts or dreams)
- Trembling
- Lowering of blood pressure, rarely accompanied by symptoms such as feeling your heartbeat, fainting or difficulty in breathing or wheezing
- Difficulty in breathing or wheezing, airway spasm
- Dry mouth, rarely accompanied by thirst and difficulty swallowing, general symptoms of indigestion such as stomachache, diarrhoea, heartburn, decreased appetite
- Rash
- Sweating, sometimes heavily
- Weakness

Uncommon: may affect up to 1 in 100 people

- Allergic reactions
- Increase in the amount of a certain hormone (ADH = antidiuretic hormone) in the blood
- Lack of water in the body (dehydration)
- Restlessness, mood swings, hallucinations, euphoric mood, decreased libido, drug dependence
- Amnesia
- Tingling or numbness (e.g. in the hands or feet)
- Convulsions, increased or decreased muscle tension or uncontrolled movements
- Reduced sensitivity to pain or touch
- Changes in taste
- Difficult speaking
- Visual impairment, reduction in the size of the pupils
- Fainting or feeling of spinning or whirling (vertigo)
- Unpleasant sensation of irregular and/or forceful beating of the heart (in the context of withdrawal), increased pulse rate, low blood pressure
- Widening of the blood vessels causing low blood pressure

- Shortness of breath, increased coughing, sore throat, runny nose, voice changes
- Difficulty swallowing, mouth ulcers, inflammation of the gum or mouth causing sore gums/mouth, flatulence (excessive gas in the stomach or bowel), belching, obstruction of the bowel (ileus)
- Increased blood levels of certain hepatic enzymes (seen in blood tests)
- Dry skin
- Problems passing urine, frequent urination
- Disturbances of sexual function, impotence
- Chills, feeling sick, injuries due to accidents resulting from decreased alertness, pain (e.g. chest pain), fluid retention (oedema), migraine, thirst, physical dependence with withdrawal symptoms, tolerance

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

- Lymph node disease
- Seizures (fits), in particular in patients having epilepsy or with a tendency to seizures
- Low blood pressure, fall in blood pressure on standing up which causes dizziness, light-headedness or fainting
- Bleeding gums
- Increased appetite
- Dark-coloured stools
- Itchy rash, blisters on the skin and mucosa (cold sores or herpes simplex), increased sensitivity to light
- Blood in urine
- Changes in body weight (loss or rise)
- Painful infection of the skin (cellulitis)

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

- Scaly rash

Not known: frequency cannot be estimated from the available data

- Sleep apnoea (breathing pauses during sleep)
- Severe allergic reactions (which may cause difficulty in breathing, dizziness, skin rashes, fever)
- Aggression
- Increased sensitivity to pain
- Cavities or tooth decay
- Painful conditions where bile cannot flow from the liver to the duodenum (cholestasis) or stomach pain due to a gallstone temporarily blocking the bile duct (biliary colic)
- Absence of menstrual bleeding
- Long term use of <Product name> 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.
- 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 of the 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 <Product name>

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.

This medicinal product does not require any special storage conditions.

In use shelf life: 3 months after first opening.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What <Product name> 10 mg/ml oral solution contains

- The active substance is oxycodone hydrochloride. Each ml contains 10 mg oxycodone hydrochloride, corresponding to 9 mg oxycodone.
- The other ingredients are sodium benzoate (E 211), saccharin sodium, citric acid monohydrate, sodium hydroxide (for pH-adjustment), Sunset yellow FCF (E 110) and water.

What <Product name> 10 mg/ml oral solution looks like and contents of the pack

<Product name> 10 mg/ml oral solution is a clear orange-red-coloured solution in an amber glass bottle with child-resistant screw cap.

<Product name> is available in bottles of:
30 ml with a 3 ml oral syringe and an adapter
100 ml with a 5 ml oral syringe and an adapter
120 ml with a 5 ml oral syringe and an adapter

A plastic oral syringe with graduation marks and an adapter is provided with the pack. The syringes are graduated with marks of 0.5 ml and 1.0 ml. Each 1 ml graduation mark of the oral syringe corresponds to 10 mg oxycodone hydrochloride.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:
<to be completed>

This leaflet was last revised in March 2025