

## Package leaflet: Information for the user

**Oxyact 5 mg film-coated tablets**  
**Oxyact 10 mg film-coated tablets**  
**Oxyact 20 mg film-coated tablets**  
oxycodone hydrochloride

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

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

### 1. What Oxyact is and what it is used for

Oxyact is a strong painkiller from the group of opioids.

Oxyact 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 Oxyact

#### Do not take Oxyact

- if you are **allergic** to oxycodone hydrochloride, peanut or soya 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**).
- if you have too much **carbon dioxide** in your blood.
- if you suffer from a severe chronic **lung disease** associated with narrowing of the airways (COPD = chronic obstructive pulmonary disease).
- if you have a certain **heart condition** known as cor pulmonale.
- if you have **asthma**.
- if you have a type of bowel obstruction called paralytic ileus.
- if you have acute **severe stomach pain** or suffer from a delayed stomach emptying.

#### Warnings and precautions

##### Talk to your doctor or pharmacist before using Oxyact

- if you are **elderly or debilitated** (weak).
- if your **lung, liver or kidney** function is severely impaired.

- if you have a certain disorder of the **thyroid gland** (myxoedema) or if your thyroid gland does not produce enough hormone (underactive thyroid).
- if you have poor adrenal gland function (your adrenal gland is not working properly) for example **Addison's disease**.
- if your **prostate** is abnormally enlarged.
- if you have a mental illness caused by alcohol or intoxication with other substances,
- if you are undergoing **alcohol withdrawal treatment**
- if you are, or were previously, **dependent on strong pain killers** (opioids).
- if you have problems with your **gall bladder**.
- if you have an **inflammation of the pancreas** which can cause severe pain in the abdomen or back.
- if you have **difficulty or pain passing urine**.
- if your doctor suspects you have intestinal paralysis (a condition where the bowel has stopped working)
- have inflammatory bowel disease.
- if you have a head injury with severe headache or discomfort – signs your **brain pressure is increased**.
- if you have **low blood pressure** or feel dizzy standing up.
- have low blood volume (hypovolaemia).
- if you suffer from **epilepsy** or are prone to fits.
- if you are also taking a type of medicine known as take so called **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
- if you suffer from constipation

#### Sleep-related breathing disorders

Oxyact can cause sleep-related breathing disorders such as sleep apnea (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.

The most significant threat of opioid overdose is a flattening and slowing of breathing (respiratory depression). This is most likely to occur in the elderly and debilitated patient and can also cause the oxygen level in the blood to decrease. This could lead to e.g. faint.

#### Tolerance, dependence and addiction

When Oxyact 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 Oxyact 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 Oxyact 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 Oxyact, 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 Oxyact).

Oxyact has a **dependence** potential. If the treatment is stopped too suddenly, withdrawal symptoms such as yawning, dilated pupils, tearing, runny nose, tremors, sweating, anxiety, restlessness, seizures, insomnia or muscle pain may occur. 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. Oxyact 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 Oxyact. Your doctor will then decide whether to reduce the dose or switch to this strong pain reliever (opioid).

Oxyact is for ingestion only (swallowing as a whole film-coated tablet). The film-coated tablets must not be dissolved and injected, as this can have serious, possibly fatal consequences.

If you need to have an operation, please tell your doctor that you are taking Oxyact.

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). This happens especially after you have received large doses for long periods of time.

### **Children**

The safety and efficacy of Oxyact in children under 12 years of age has not been established. Therefore, use of Oxyact is not recommended in this age group.

### **Anti-Doping Warning**

Athletes must be aware that this medicine may cause a positive reaction to “anti-doping” tests. Use of Oxyact as a doping agent may become a health hazard.

### **Other medicines and Oxyact**

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

Concomitant use of Oxyact 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 Oxyact 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:

- 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 (such as tranylcypromine, phenelzine, isocarboxazid, moclobemide or linezolid),
- 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.

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.

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 (such as tizanidine)
- 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 phenprocoumon).

### **Oxyact with drink and alcohol**

Oxyact 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.

Oxyact should be avoided in patients with a history of or present alcohol and drug abuse.

Grapefruit juice may increase the levels of oxycodone 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 Oxyact **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, the baby may have breathing problems (respiratory depression).

#### ***Breast-feeding***

Breast-feeding **should be discontinued** during treatment with Oxyact. Oxycodone hydrochloride passes into breast milk and may cause sedation and shallow and slow breathing (respiratory depression) in the breast-fed child. Therefore, a risk for the suckling infant cannot be excluded in particular following intake of multiple doses of Oxyact

### **Driving and using machines**

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
  - The medicine has been prescribed to treat a medical or dental problem and
  - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
  - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

### **Oxyact contains lactose**

Oxyact contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### **Oxyact contains soya**

Oxyact contains soya. If you are allergic to peanut or soya, do not use this medicinal product.

### **Oxyact contains Ponceau 4R (E 124) (Oxyact 5 mg only)**

Oxyact 5 mg film-coated tablets contain the colouring agent Ponceau 4R (E 124) which may cause allergic reactions.

## **3. How to take Oxyact**

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 Oxyact, 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 Oxyact).

### **Dosage**

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

**Your doctor will adjust your dose** according to pain intensity and to your individual susceptibility.

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.

Please talk to your doctor, if you think that the effect of Oxyact is too weak or too strong.

**If not prescribed otherwise by your doctor, the recommended dose is**

- ***for adults and adolescents (from 12 years and older):***

The usual starting dose is 5 mg every 6 hours. The dosing interval of Oxyact may be reduced to 4 hours if required. Oxyact should not be taken more than 6 times a day.

However, your doctor will prescribe the dose required to treat your pain. If you find that you are still in pain whilst taking these tablets, discuss this with your doctor.

- ***for the elderly (65 years and older):***

Elderly patients with normal liver and/or kidney function may take the same doses as given for adults above.

- ***for patients with kidney and/or liver disorders:***

If you have liver or kidney problems and you have not yet received opioids, you should start with half the recommended adult dose.

- ***for other risk patients:***

If you are light or if your body metabolizes medicines more slowly, the starting dose should be half the recommended adult dose.

- ***for children (below 12 years):***

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

For patients who have been **treated with other strong pain killers (opioids) before**, the doctor may prescribe a higher starting dose.

Your doctor will decide how much you should take every day after that, 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 you experience pain between doses of Oxyact, you may require higher doses of Oxyact. Please talk to your doctor if you have this problem.

If you require long-term treatment of severe pain, you will be switched to oxycodone hydrochloride prolonged-release tablets.

### **Method of administration**

Oral use.

Take this medicine **with a sufficient amount of liquid** (e.g. ½ glass of water) **every 4 to 6 hours** as scheduled by your doctor. You can take this medicine with or without food.

### **Duration of application**

Your doctor will tell you how long to take Oxyact.

Do not stop your Oxycodone hydrochloride G.L treatment without talking to your doctor (see “If you stop taking Oxyact”).

If you take Oxyact for a long time, you should monitor your therapy and discuss it with your doctor regularly. This is necessary in order to achieve the best possible pain therapy, i.e. to enable timely treatment of occurring side effects as well as a decision on dose adjustment and continuation of treatment.

Please talk to your doctor or pharmacist if you have the impression that the effect of Oxyact is too strong or too weak.

### **Opening instructions for the blister:**

This medicine is in child-resistant packaging. The film-coated tablets must be pressed out firmly of the blister.

### **If you take more Oxyact than you should**

**Contact a doctor immediately if you have taken more tablets than you have been prescribed.**

Overdosing can cause:

- constriction of the pupils,
- flattening and slowing of 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 - possibly with fatal outcome - can occur.

Never put yourself in situations that require heightened attention, such as: driving a car.

### **If you forget to take Oxyact**

If you take a smaller dose of Oxyact 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.

Please note that you are supposed to take this medicine at intervals of 4 to 6 hours.

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

### **If you stop taking Oxyact**

Do not stop treatment without first speaking with your doctor.

If you stop taking Oxyact, this may trigger withdrawal symptoms (e.g. yawning, dilated pupils, tearing, runny nose, tremors, sweating, anxiety, restlessness, seizures, insomnia or muscle pain). Therefore, it may be advisable for your doctor to reduce the dose gradually.

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

## **4. Possible side effects**

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

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

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

**Other side effects**

**Very common:** may affect more than 1 in 10 people

- sleepiness to drowsiness, dizziness, headache.
- constipation, this side effect can be counteracted by preventive measures (such as drinking plenty and eating a high-fiber diet)
- feeling or being sick, vomiting. Your doctor will prescribe an appropriate medicine to treat these symptoms.
- itching.

**Common:** may affect up to 1 in 10 people

- changes in mood and personality (anxiety, confusion, depression, nervousness, sleep disorders, abnormal thoughts) decreased activity, restlessness, increased activity.
- uncontrolled trembling or shaking movements in one or more parts of your body, feeling weak.
- difficulty in breathing or wheezing.
- dry mouth, hiccups, general symptoms of indigestion such as stomachache, diarrhoea, heartburn.
- skin reactions/rash, sweating.
- weakness.
- decreased appetite up to loss of appetite
- dysuria, increased urge to urinate

**Uncommon:** may affect up to 1 in 100 people

- a need to take increasingly higher doses of Oxyact to gain the same level of pain relief (tolerance)
- injuries due to accidents resulting from reduced alertness
- allergic reactions.
- increase in the amount of a certain hormone (ADH = antidiuretic hormone) in the blood.
- lack of water in the body (dehydration).
- agitation, mood swings, euphoric mood,
- decreased libido
- perception disorders (e.g hallucinations)
- epileptic seizures (fits), in particular in patients suffering from epilepsy or with a tendency to seizures
- loss of memory, concentration impaired, migraine
- increased or decreased muscle tension, tics, tingling or numbness (e.g. in the hands or feet),
- speech disorders, reduced sensitivity to pain or touch, abnormal coordination, taste changes.
- visual impairment, reduction in the size of the pupils.
- hearing impaired, feeling of spinning or whirling (vertigo).
- unpleasant sensation of irregular and/or forceful beating of the heart, increased pulse rate.
- widening of the blood vessels causing low blood pressure.
- increased coughing, sore throat, voice changes.
- difficulty swallowing, mouth ulcers, sore gums, flatulence (excessive gas in the stomach or bowel), belching, obstruction of the bowel (ileus).
- increased blood levels of certain liver enzymes.
- dry skin.
- problems passing urine, frequent urination.

- decreased sexual perception and inability to have or maintain an erection during sexual intercourse.
- decrease in the concentration of sex hormones that can affect sperm production in men or the "period" cycle (menstruation) in women
- chills,
- pain (e.g. chest pain), feeling sick
- fluid retention (oedema - e.g. in the hands, ankles, or legs, especially at the ankles), thirst

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

- feeling weak especially when getting up
- lymph node disease.
- muscle spasms/bleeding gums, dark-coloured stools, tooth decay.
- itchy rash, blisters on the skin and mucosa (cold sores or herpes).
- changes in body weight (loss or rise).

**Not known:** frequency cannot be estimated from the available data

- aggression
- increased sensitivity to pain
- sleep apnoea (breathing pauses during sleep)
- severe allergic reactions.
- cavities or tooth decay.
- obstructed bile secretion, biliary colic (which causes stomach pain).
- absence of menstrual bleeding.
- long term use of Oxyact 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 Yellow Card Scheme, Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

## 5. How to store Oxyact

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

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

This medicinal product does not require any special storage conditions.

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 Oxyact contains**

**The active substance is** oxycodone hydrochloride.

### ***Oxyact 5 mg film-coated tablets***

**Each** film-coated tablet contains 5 mg oxycodone hydrochloride equivalent to 4.48 mg oxycodone.

### ***Oxyact 10 mg film-coated tablets***

**Each** film-coated tablet contains 10 mg oxycodone hydrochloride equivalent to 8,97 mg oxycodone.

### ***Oxyact 20 mg film-coated tablets***

**Each** film-coated tablet contains 20 mg oxycodone hydrochloride equivalent to 17,93 mg oxycodone.

## **The other ingredients are**

Tablet core: sodium starch glycolate type A, lactose monohydrate, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate.

Film coating: polyvinyl alcohol, talc, titanium dioxide (E 171), macrogol 3350 (E 1521), lecithin soya (E 322), indigo carmine, aluminium lake (E 132), Ponceau 4R, aluminium lake (E 124) (5 mg film-coated tablets only), iron oxide yellow (E 172) (20 mg film-coated tablets only).

## **What Oxyact looks like and contents of the pack**

### ***Oxyact 5 mg film-coated tablets***

Oxyact 5 mg film-coated tablets are dark blue, round, vaulted and biconvex film-coated tablets.

### ***Oxyact 10 mg film-coated tablets***

Oxyact 10 mg film-coated tablets are middle blue, vaulted, oblong film-coated tablets with break score on both sides. The tablet can be divided into equal halves.

### ***Oxyact 20 mg film-coated tablets***

Oxyact 20 mg film-coated tablets are light blue, vaulted, oblong film-coated tablets with break score on both sides. Length: 12.1 mm, thickness: 3.5 mm, width: 5.2 mm.

The tablet can be divided into equal halves.

Oxyact 5/10/20 mg are available in PVC/PVdC/Aluminium Blisters containing 10, 20, 30, 56 or 60 film-coated tablets

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

G.L. Pharma GmbH, Schlossplatz 1, 8502 Lannach, Austria

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