

## 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 used to treat **severe pain**, which requires treatment with an opioid analgesics because other painkillers have not been effective.

#### 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 or anyone in your family have ever abused or been **dependent on alcohol**, prescription medicines or **illegal drugs** ("addiction").
- if you are a **smoker**.
- if 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 are, or were previously, **dependent on strong pain killers** (opioids).
- if you have an inflammation of the **pancreas** (pancreatitis) or if you have problems with your **gall bladder**.
- if you have **difficulty or pain passing urine**.
- if your **brain pressure** is **increased**.
- if you have **low blood pressure** or feel dizzy standing up.
- 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.

#### Dependence and tolerance

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.

Repeated use of Oxyact may lead to dependence and abuse which may result in life-threatening overdose. If you have concern that you may become dependent on Oxyact, it is important that you consult your doctor.

Oxyact has a **dependence** potential. If the treatment is stopped too suddenly, withdrawal symptoms 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.

#### **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.

#### **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.

#### **Other medicines and Oxyact**

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

The risk of side effects is increased if you take Oxyact at the same time as medicines which affect the way the brain works. For example, you may feel very sleepy, or breathing problems may get worse.

Medicines that affect the way the brain works include:

- other strong pain killers (opioids),
- sleeping pills and tranquillisers,
- antidepressants,

- medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics),
- other medicines which act on the nervous system (phenothiazines, neuroleptics),
- medicines used to treat Parkinson's disease (so-called MAO inhibitors, see also section "Warnings and precautions").

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.

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.

#### Further interactions may occur with

- cimetidine (used to manage excess of gastric acid). It may prolong the duration of effects of Oxyact in your body.
- medicines against blood clotting (e.g. warfarin). Oxyact may influence their effects.
- certain antibiotics, antifungal medicines and medicines containing St. John's Wort.

#### **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.

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

Breast-feeding **should be discontinued** during treatment with Oxyact Oxycodone hydrochloride passes into breast milk. 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 and soya and Ponceau 4R (E 124) (Oxyact 5 mg only).**

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

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.

**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. 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 (12 years and older):***

The usual starting dose is 5 mg oxycodone hydrochloride every 6 hours. If needed, the dosing interval may be shortened to 4 hours by your doctor. However, Oxyact should not be taken more often than 6 times a day.

- ***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, or with low body weight:***

Your doctor may prescribe a lower starting dose.

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 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.

**Opening instructions for the blister:**

This medicine is in child-resistant packaging. The film-coated tablets have to 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.**

**Symptoms of overdose are:** a reduction in the size of the pupils, breathing problems, feeling weak in the muscles (low muscle tone, hypotonia), and a fall in blood pressure. In severe cases drowsiness or fainting due to a failure of the circulatory system (circulatory collapse), impairment of thinking and of movement, loss of consciousness (coma), reduced pulse rate and accumulation of fluid in the lungs may occur.

Use of **large amounts** of Oxyact **may result in death.**

**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 as **withdrawal symptoms** may occur.

If you do not require treatment with Oxyact anymore, your doctor will advise you on how to **reduce the dose gradually** to prevent the occurrence of withdrawal symptoms.

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, 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

- 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, hallucinations, derealisation, euphoric mood, decreased libido, drug dependence.
- loss of memory, concentration impaired. tingling or numbness (e.g. in the hands or feet), increased or decreased muscle tension, tics, fainting, 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.
- shortness of breath, 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.
- decreased functional activity of the gonads. 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 (see section 3 'If you stop using Oxyact')
- a need to take increasingly higher doses of Oxyact to gain the same level of pain relief (tolerance).
- epileptic seizures (fits), in particular in patients suffering from epilepsy or with a tendency to seizures.
- a condition where you breathe more slowly and weakly than expected (respiratory depression)

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

- lymph node disease.
- muscle spasms, low blood pressure.
- bleeding gums, increased appetite, dark-coloured stools.
- 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

- Sleep apnoea (breathing pauses during sleep)
- severe allergic reactions.
- aggression.
- increased sensitivity to pain.
- 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.

### 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.

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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