Package leaflet: Information for the user

<invented name> 5 mg prolonged-release tablets
<invented name> 10 mg prolonged-release tablets
<invented name> 20 mg prolonged-release tablets
<invented name> 40 mg prolonged-release 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 <invented name> is and what it is used for

<invented name> is indicated in adults and adolescents (from 12 years of age).
<invented name> contains the active ingredient oxycodone hydrochloride, which is a strong analgesic or "painkiller" and belongs to a group of medicines called opioids.
It is used for the relief of severe pain, which can be adequately managed only with opioid analgesics.
Do not take this medicine other than prescribed by your doctor. It is not for use on an "as-needed" basis for relief of mild pain, ordinary aches, or the symptoms of colds or the flu.

2. What you need to know before you take <invented name>

Do not take <invented name>:

- if you are allergic to oxycodone hydrochloride or any of the other ingredients of this medicine (listed in section 6),
- if you suffer from severe breathing problems, such as severe respiratory depression (where you breathe more slowly or weakly than expected),
- if you suffer from elevated carbon dioxide levels in the blood (hypercapnia),
- if you suffer from a severe lung disease associated with narrowing of the airways (chronic obstructive airways disease),
- if you have a heart problem caused by long-term lung disease (cor pulmonale),
- if you suffer from severe bronchial asthma,
- if you have a condition where the small bowel does not work properly (paralytic ileus),

Warnings and precautions

Talk to your doctor or pharmacist before taking <invented name>:
- if you are elderly or weak,
- if you have severe lung-, liver- or kidney problems,
- if you have a disease of the thyroid gland (myxoedema) or underactive thyroid gland (hypothyroidism),
- if your adrenal glands are not producing enough hormones (adrenal insufficiency, Addison's disease),
- if you have an enlarged prostate gland (prostate hypertrophy),
- if you have a mental disorder as a result of an intoxication caused by, for example, alcohol (toxic psychosis),
- if you suffer from a state of violent mental agitation caused by alcohol poisoning (alcoholism, delirium tremens),
- if you have known opioid dependence,
- if you have inflammation of the pancreas (pancreatitis),
- if you have gallstones (biliary calculi),
- if you have obstructive and inflammatory intestinal diseases. Stop taking <invented name> immediately if you think your intestines have stopped working properly (paralytic ileus),
- if you have conditions involving increased brain (cerebral) pressure,
- if you have problems with your circulatory system, if you have epilepsy or are prone to fits (convulsions),
- if you use MAO inhibitors.

If any of the above applies to you or has in the past, talk to your doctor.

The most serious side effect of an opioid overdose is a condition where you breathe more slowly or weakly than expected (respiratory depression). This occurs most commonly in elderly or vulnerable patients.
Opioids may also cause a severe drop in blood pressure in susceptible individuals. If you are affected by these side effects, consult a doctor immediately.

If you are going to have an operation, make sure you tell your doctor that you are taking <invented name>.

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

Long term use / Dependence

Patients may develop a tolerance with long-term use of <invented name>. Therefore they may require higher doses of <invented name> to achieve the desired pain control. Prolonged use of <invented name> in chronic pain patients may lead to physical dependence. If treatment is stopped abruptly withdrawal symptoms that include yawning, mydriasis, lacrimation, rhinorrhoea, tremor, hyperhidrosis, anxiety, agitation, palpitations, convulsions and insomnia may occur. When therapy with <invented name> is no longer necessary, it may be advisable to reduce the daily dose gradually in order to prevent withdrawal symptoms.

<invented name> has a primary dependence potential. When used as instructed in chronic pain patients, the risk of physical and mental dependence is clearly reduced and must be assessed correspondingly relative to the benefits. Please discuss this with your doctor.

Athletes should be aware that this medicine may cause a positive reaction to "anti-doping tests". Use of <invented name> as a doping agent may become a health hazard.

Children

<invented name> has not been tested in children under 12 years of age. Therefore safety and efficacy are not established and <invented name> is not recommended in children under 12 years of age.

Other medicines and <invented name>

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

Taking <invented name> at the same time as the following medicines may increase the side effects of <invented name> (particularly breathing problems):

- medicines acting on the central nervous system, such as sleeping and calming medicines (sedatives, hypnotics),
- other medicines which affect the nervous system (phenothiazines, neuroleptics),
- antidepressants,
- medicines for allergies or vomiting (antihistamines, anti-emetics),
- other strong painkillers (opioids),
- alcohol.

Taking <invented name> at the same time as the following medicines may intensify specific side effects of <invented name> (such as constipation, dry mouth or problems urinating):

- medicines with anti-cholinergic effects, such as other medicines which act upon the nervous system (medicines to treat psychiatric or mental disorders), medicines for allergies or vomiting (antihistamines, antiemetics),
- medicines for Parkinson's disease.

If you are taking <invented name> at the same time as medicines that thin your blood (coumarin-type anti-coagulants), your blood clotting time may be speed up or slowed down. This is measured by a test called the INR that checks how long it takes for your blood to clot.

Antibiotics (such as clarithromycin, erythromycin and telithromycin), antifungal medicines (such as ketoconazole, voriconazole, itraconazole and posaconazole), protease inhibitors (such as boceprevir, ritonavir, indinavir, nelfinavir and saquinavir), cimetidine (gastric acid inhibitor - a medicine for stomach ulcers, indigestion or heartburn) and grapefruit juice as well as paroxetine and quinidine may prevent the metabolism of oxycodone hydrochloride.

Some medicines, such as rifampicin, carbamazepin, phenytoin and St John's Wort may induce the metabolism of oxycodone hydrochloride.

These tablets must not be used together with a monoamine oxidase inhibitor, or if you have taken this type of medicine in the last two weeks.

<invented name> with food, drink and alcohol

You can take <invented name> with or without food.

Drinking alcohol whilst taking <invented name> may make you feel more sleepy or increase the risk of serious side effects such as shallow breathing with a risk of stopping breathing, and loss of consciousness. It is recommended not to drink alcohol while you're taking <invented name>.

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.
<invented name> should not be taken during pregnancy unless clearly necessary. There are only limited data from the use of oxycodone hydrochloride in pregnant women. Oxycodone

hydrochloridecrosses the placenta into the blood circulation of the unborn child. The long-term use of <invented name> during pregnancy may lead to withdrawal symptoms in newborn infants. If taken during birth, breathing problems (respiratory depression) may occur in the child.

You should not take <invented name> if you are breast-feeding as oxycodone passes into breast milk.

Driving and using machines

<invented name> may impair your ability to drive or operate machinery. This is particularly likely:
- when you start the treatment with <invented name>,
- after a dose increase or product rotation (the use of alternative medicines, to reduce side effects),
- if <invented name> is combined with alcohol or with medicines, which act on the central nervous system.

General driving restrictions may not apply during stable treatment; your doctor makes this decision based upon the individual situation. Please discuss with your doctor whether or not, or under which conditions you may drive.

3. How to take <invented name>

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

Your doctor will adjust the dosage to the intensity of the pain and to your personal sensitivity. Take the prescribed number of prolonged-release tablets twice daily.

Use in adults and adolescents (from 12 years of age)

The usual starting dose is 10 mg oxycodone hydrochloride every 12 hours. Take 1 prolonged-release tablet in the morning and 1 prolonged-release tablet in the evening.

While symmetric (same dose in the morning and in the evening), around-the-clock, 12 hourly dosing is appropriate for the majority of patients, some patients may benefit from asymmetric dosing (different dose in the morning and in the evening) tailored to their pain pattern. Your doctor will decide on the best treatment schedule to suit your needs.

Your doctor will decide on any necessary dose adjustments during treatment depending on your previous dosage. If you have already been treated with opioids, your treatment with <invented name> may be started at a higher dose.

Some patients taking <invented name> on a fixed time schedule require a fast-acting painkiller for quick relief from breakthrough pain. <invented name> prolonged-release tablets are not intended for the treatment of breakthrough pain.

Your doctor will monitor you regularly to ensure you receive the best possible pain relief treatment. Treatment of side effects and the need to continue treatment will also be monitored.

Please speak to your doctor or pharmacist if you feel that the effect of <invented name> is too strong or too weak.

Tumour and no-tumour related pain

For the treatment of non-tumour related pain, 40 mg of oxycodone hydrochloride is normally a sufficient daily dose; however, higher doses may be necessary. Patients with tumour related pain

normally require doses of 80 to 120 mg of oxycodone hydrochloride, which, in exceptional cases, may be increased up to 400 mg of oxycodone hydrochloride.

Older people

In elderly patients without kidney and/or liver problems, dosage adjustment is usually not necessary.

High-risk patients

Patients with kidney and/or liver problems who have not received opioids before should initially take half of the recommended adult dose. This also applies to patients with low body weight and patients who metabolise medications at slower rates.

Children

<invented name> has not been tested in children under 12 years of age. Therefore safety and efficacy are not established and <invented name> is not recommended in children under 12 years of age.

Method of administration and duration of use

<invented name> is for oral use only.The tablets should never be injected as this may lead to serious side effects, which may be fatal.

Swallow the prolonged-release tablets with sufficient liquid (half a glass of water) in the morning and evening in accordance to a fixed time schedule (e.g. in the morning at 8 a.m., in the evening at 8 p.m.). You can take your tablets with or without food.

<invented name> should not be taken with alcoholic beverages.

Swallow the tablets whole, and do not cut, break, chew, crush, or dissolve the tablets. Taking cut, broken, chewed, crushed or dissolved tablets leads to speedier release of the active substance and to the absorption of a potentially lethal dose of the active substance oxycodone hydrochloride (see under "If you take more <invented name> than you should").

Oxycodone should not to be administered for longer than absolutely necessary. If long-term pain treatment is necessary in view of the nature and severity of the illness, careful and regular monitoring should be carried out to establish whether and to what extent further treatment is necessary. When the patient no longer requires opioid therapy, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal.

If you take more <invented name> than you should

If you have taken more medicine than prescribed, you should inform your doctor immediately.

The following may occur:
- narrowed pupils,
- respiratory depression,
- somnolence progressing up to stupor or loss of consciousness (coma),
- decreased tension of skeletal muscles,
- slowed pulse rate and drop in blood pressure,
- loss of consciousness (coma), water retention in the lung and circulatory collapse may occur in more severe cases and may lead to death.

Never engage in situations which require a high degree of concentration, such as driving.
Accidental overdose by a child is dangerous and may be fatal.

If you forget to take <invented name>

If you take a smaller dose of <invented name> than prescribed, or if you have completely forgotten to take your dose, this will lead to unsatisfactory and/or insufficient pain relief.

If you have forgotten to take your dose, and your next usual dose is scheduled more than 8 hours later: Take the forgotten dose. You may then continue to follow your usual schedule.

If the time until your next dose is less than 8 hours, take your dose but postpone the next dose by 8 hours.
As a matter of principle, you should never take more than one dose of <invented name> within any 8 hour period.

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

If you stop taking <invented name>

Do not stop taking <invented name> without consulting your doctor.

If treatment with <invented name> is no longer necessary, gradual reduction of the daily dosage may be advisable. If treatment is stop abruptly, withdrawal symptoms may occur.

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.

The most common side effects are nausea (especially at the beginning of therapy) and constipation. Constipation may be countered by preventive measures (such as drinking plenty of fluids, nutrition, rich in fibre); your doctor may prescribe a treatment to overcome this problem.
If you experience nausea or vomiting, your doctor may prescribe medication for you.

Important side effects or signs to look out for. If you are affected by these side effects, consult a doctor immediately:

- The most serious side effect is a condition where you breathe more slowly or weakly than expected (respiratory depression). It can occur most commonly in elderly or vulnerable patients. Opioids may cause a severe drop in blood pressure in susceptible individuals.

- The active substance oxycodone hydrochloride can cause respiratory depression, narrowing of the pupils, cramping of the bronchial muscles, as well as a depression of the cough reflex.

Other possible side effects:

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

- Constipation, vomiting, nausea
- Fatigue and/or drowsiness (sedation), dizziness, headache
- Itching (pruritus)

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

- Abdominal pain, diarrhoea, dry mouth, hiccups, indigestion (dyspepsia)
- Decreased appetite up to loss of appetite

- Altered mood and personality changes (e.g. anxiety, depression, euphoric mood), decreased activity, restlessness, increased activity, agitation, nervousness, insomnia, abnormal thinking, confusion
- Loss of consciousness (syncope), tingling or numbness in the hands or feet (paraesthesia), shaking (tremor)
- Drop in blood pressure (hypotension)
- *Difficulty breathing (dyspnoea, bronchospasm)*
- Skin reactions/rash
- Urinary retention, difficulty or pain on passing urine (dysuria), increased urge to urinate
- Chills, general weakness, sweating, hyperhidrosis

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

- Physical dependence including withdrawal symptoms, pain (e.g. chest pain), a general feeling of unease or lack of health (malaise), swelling from excessive accumulation of fluid (edema), peripheral edema, thirst
- Injuries from accidents
- Allergic reactions (hypersensitivity)
- Perception disturbances (e.g. hallucination, derealisation), reduced libido, affect lability, drug dependence
- Difficulty in concentrating, migraine, distorted sense of taste (dysgeusia), increased muscle tension (hypermyotonia), involuntary muscle contractions, reduced sense of touch (hypoaesthesia), abnormal coordination, epileptic seizures (especially in persons with epileptic disorder or predisposition to seizures), amnesia, speech disorder
- Visual impairment, miosis
- Hearing difficulty, vertigo
- Increase in pulse rate (tachycardia), palpitations (in the context of withdrawal syndrome)
- Vasodilatation
- Vocal changes (dysphonia), cough, respiratory depression
- Oral ulcers, inflammation in the mouth (stomatitis), flatulence, difficult swallowing (dysphagia), eructation, blockage of the intestine (ileus)
- Erectile dysfunction
- Dehydration
- Increase of liver enzymes levels
- Dry skin
- A need to take increasingly higher doses to obtain the same level of pain relief (tolerance)

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

- Melaena (abnormally dark tarry feces containing blood), dental changes, gum bleeding
- Herpes simplex
- Increased appetite
- Weight increase, weight decrease
- Orthostatic hypotension
- Itching rash (urticaria)

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

- Suppression of cough reflex
- Biliary colic (gallstones), cholestasis
- Amenorrhoea (abnormal lack of menstruation)
- Exaggerated allergic reaction (anaphylactic reaction)
- Aggression
- Hyperalgesia

- Dental caries

As with all strong painkillers, there is a risk that you may become addicted or reliant on these tablets.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any 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 <invented name>

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 carton after "Expiry date". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 <invented name> contains

- The active substance is oxycodone hydrochloride.
  <invented name> 5 mg prolonged-release tablets
  Each prolonged-release tablet contains 5 mg of oxycodone hydrochloride equivalent to 4.5 mg of oxycodone

  <invented name> 10 mg prolonged-release tablets
  Each prolonged-release tablet contains 10 mg of oxycodone hydrochloride equivalent to 9.0 mg of oxycodone.

  <invented name> 20 mg prolonged-release tablets
  Each prolonged-release tablet contains 20 mg of oxycodone hydrochloride equivalent to 17.9 mg of oxycodone

  <invented name> 40 mg prolonged-release tablets
  Each prolonged-release tablet contains 40 mg of oxycodone hydrochloride equivalent to 35.9 mg of oxycodone.

- The other ingredients are:

Hypromellose, polyvinyl acetate, povidone K30, sodium lauryl sulphate, silica, microcrystalline cellulose, silicon dioxide, magnesium stearate, dibutyl sebacate, ethylcellulose, cetyl alcohol, talc.

What <invented name> looks like and contents of the pack

<invented name> 5 mg prolonged-release tablets
<invented name> 5 mg prolonged-release tablets are white to off-white, 9.6 x 4.8 mm, elliptic, biconvex, coated tablet, embossed with "5" on one side and "LT" on the other side.

<invented name> 10 mg prolonged-release tablets

<invented name> 10 mg prolonged-release tablets are white to off-white, 9.6 x 4.8 mm, elliptic, biconvex, coated tablet, embossed with “10” on one side and “LT” on the other side.

<invented name> 20 mg prolonged-release tablets
<invented name> 20 mg prolonged-release tablets are white to off-white, 11 x 5.5 mm, elliptic, biconvex, coated tablet, embossed with “20” on one side and “LT” on the other side.

<invented name> 40 mg prolonged-release tablets
<invented name> 40 mg prolonged-release tablets are white to off-white, 11 x 5.5 mm, elliptic, biconvex, coated tablet, embossed with “40” on one side and “LT” on the other side.

<invented name> prolonged release tablets is available in pack sizes of 10, 20, 28, 30, 40, 50, 56, 60, 100 and 112 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder

[to be completed nationally]

Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany:	Redocam 5 mg / 10 mg / 20 mg / 40mg Retardtabletten
Estonia:	Pancod
Latvia:	Pancod 5 mg / 10 mg / 20 mg / 40mg ilgstošās darbības tabletes
Lithuania:	Pancod 5 mg / 10 mg / 20 mg / 40mg, pailginto atpalaidavimo tabletės
Poland:	Pancod
Romania:	Pancod 5 mg / 10 mg / 20 mg / 40mg comprimate cu eliberare prelungită
Slovakia:	Pancod 5 mg / 10 mg / 20 mg / 40mg, tableta s predĺženým uvoľňovaním
Slovenia:	Redocam 5 mg / 10 mg / 20 mg / 40mg tablete s podaljšanim sproščanjem

This leaflet was last revised in {MM/YYYY}.

[to be completed nationally]