PACKAGE LEAFLET: Information for the user

<Invented name>

{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 or nurse..
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet, See section 4.

What is in this leaflet:

1. What Oxycodon-HCl Accord is and what it is used for

This medicinal product contains the active ingredient oxycodone which belongs to a group of medicines called strong analgesics or "painkillers".
[Invented name] is used to treat severe pain, which can be adequately managed only with opioid analgesics.
[Invented name] is indicated in adults and adolescents above 12 years of age.

2. What you need to know before you take Oxycodon-HCl Accord

Do not take Oxycodon-HCl Accord tablets if you:
- are allergic to oxycodone hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- have breathing problems, such as chronic obstructive lung disease, severe bronchial asthma or severe respiratory depression. Your doctor will have told you if you have any of these conditions. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected;
- have a condition where the small bowel does not work properly (paralytic ileus), your stomach empties more slowly than it should (delayed gastric emptying) or you have severe pain in your abdomen;
- have a heart problem after long-term lung disease (cor pulmonale);
- have moderate to severe liver problems. If you have other long- liver problems you should only take these tablets if recommended by your doctor;
- have ongoing problems with constipation;

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- are under 12years of age.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Oxycodon-HCl Accord
- if you are elderly or weakened;
- if you have an under-active thyroid gland (hypothyroidism), as you may need a lower dose
- if you have liver or kidney problems
- if you have myxoedema (a thyroid disorder with dryness, coldness and swelling [‘puffiness’] of the skin affecting the face and limbs;

-if you have poor adrenal gland function (your adrenal gland is not working properly which may cause symptoms including weakness, weight loss, dizziness, feeling or being sick), e.g. Addison’s disease;
- if you have low blood pressure (hypotension);
- if you have low blood volume (hypovolaemia); this can happen with severe external or internal bleeding, severe burns, excessive sweating, severe diarrhoea or vomiting;
- if you have a mental disorder as a result of an infection (toxic psychosis);
- if you have problems with your gall bladder or bile duct;
- if you have inflammatory bowel disease;
- if you have an enlarge prostate gland, which causes difficulty in passing urine (in men);
- if you are or have ever been addicted to alcohol or drugs or have a known opioid dependence;
- if you suffer from inflammation of the pancreas (which causes severe pain in the abdomen and back)
- if you have a severe headache or feel sick as this may indicate that the pressure in your skull is increased
- if you have breathing problems such as severe pulmonary disease. Your doctor will have told you if you have this condition. Symptoms may include breathlessness and coughing;

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- If you have previously suffered from withdrawal symptoms such as agitataion, anxiety, shaking or sweating, upon stopping taking alcohol or drugs.
- have an increased sensitivity to pain;
- need to take increasingly higher doses of Oxycodon HCl to gain the same level of pain relief (tolerance).

If you are going to have an operation, please tell the doctor at the hospital that you are taking these tablets.

The administration of chewed or crushed tablets leads to a rapid release and absorption of a potentially fatal dose of oxycodone (see section 3)

Children and adolescents
Oxycodon-HCl Accord has not been investigated in children under 12 years. Safety and efficacy have not been established therefore use in children under 12 years of age is not recommended.

Patients older than 65 years
Frail geriatric patients who have not taken opioids before usually need to start with the lowest dose.

Anti-doping warning
Athletes should be aware that this medicine may cause a positive reaction to “anti-doping tests”. Use of Oxycodon-HCl Accord as a doping agent may become a health hazard.

Other medicines and Oxycodon-HCl Accord

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you take these tablets with some other medicines, the effect of these tablets or the other medicine may be changed.

Tell your doctor or pharmacist if you are taking:

- a type of medicine known as a monoamine oxidase inhibitor or you have taken this type of medicine in the last two weeks;
- medicines to help you sleep or stay calm (for example tranquillisers, hypnotics or sedatives);
- medicines to treat depression (such as paroxetine);
- medicines to treat psychiatric or mental disorders (such as phenothiazines or neuroleptic drugs);
- other strong analgesics (‘painkillers’);
- muscle relaxants;
- medicines to treat high blood pressure;
- quinidine (a medicine to treat a fast heart beat);
- cimetidine (a medicine for stomach ulcers, indigestion or heartburn);
- antifungal medicines (such as ketoconazole, voriconazole, itraconazole and posaconazole);
- antibiotics (such as clarithromycin, erythromycin or telithromycin);
- medicines known as ‘protease inhibitors’ to treat HIV (e.g. boceprevir, ritonavir, indinavir, nelfinavir or saquinavir);
- rifampicin (to treat tuberculosis);
- carbamazepine (a medicine to treat sezures, fits or convulsions and certain pain conditions);
- phenytoin (a medicine to treat seizures, fits or convulsions);
- a herbal remedy called St. John’s Wort (also known as *Hypericum perforatum*).
- antihistamines;
- medicines to treat Parkinson’s disease.

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

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.

Oxycodon-HCl Accord with food and drink and alcohol

Drinking alcohol whilst taking Oxycodon-HCl Accord prolonged release tablets 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 Oxycodon-HCl Accord prolonged release tablets.
You should avoid drinking grapefruit juice during your treatment with this medicine.

You can take Oxycodon-HCl Accord with or without food.

Pregnancy,breast-feeding and fertility
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
You should not take Oxycodon-HCl Accord during pregnancy. There are limited data from the use of Oxycodone in pregnant women. Infants born to mothers who have received oxycodone during the last 3-4 weeks before labour can cause severe breathing difficulties in the newborn. Withdrawal symptoms may be observed in the newborn of mothers undergoing treatment with oxycodone.

Breast-feeding
Oxycodone may pass into breast milk and may cause breathing difficulties in the newborn. Oxycodone-HCl should therefore not be used during breast-feeding**.**

Driving and using machines
Oxycodone impairs alertness and reactivity to such an extent that the ability to drive and operate machinery is affected or ceases altogether. With stable therapy, a general ban on driving a vehicle may be not necessary. The treating physician must assess the individual situation. Please discuss with your doctor whether or under what conditions you can drive a vehicle.
To look at the possible side effects affecting the motor skills and concentration see section 4. "Possible side effects".

Oxycodon-HCl Accord contains Sucrose

This medicinal product contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before you take this medicinal product.

3. HOW TO TAKE OXYCODON-HCL ACCORD How to take Oxycodon-HCl Accord

These tablets have been prescribed for you by your doctor to relieve moderate to severe pain over a period of 12 hours.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
For doses not realiable/practicable with this medicinal product other strengths and medicinal products are available.

The recommended dose is
Oxycodon-HCl Accord 5 mg/ 10 mg/ 20 mg/ 40 mg/ 80 mg prolonged-release tablets
Adults and adolescents (over 12 years of age)
The usual initial dose is 10 mg of oxycodone hydrochloride in 12 hourly intervals.

Further determination of the daily dose, the division into the single doses and any dose adjustments during the further course of therapy are performed by the treating physician and depend on the previous dosage.
Patients who have already taken opioids can start treatment with higher dosages taking into account their experience with opioid treatment.
Some patients who receive Oxycodon-HCl Accord prolonged-release tablets according to a fixed schedule need rapidly acting painkillers as rescue medication to control breakthrough pain. Oxycodon-HCl Accord prolonged-release tablets are not intended for the treatment of breakthrough pain.
For the treatment of non-cancer pain a daily dose of 40 mg of oxycodone hydrochloride is generally sufficient, but higher dosages may be necessary. Patients with cancer pain usually require dosages from 80 to 120 mg of oxycodone hydrochloride which may be increased up to 400 mg in individual cases.
The treatment needs to be controlled regularly with regard to pain relief and other effects in order to achieve the best pain therapy possible as well as to be able to treat any occurring side effects in good time and to decide whether treatment should be continued.

Patients older than 65 years
In frail geriatric patients who have not yet taken opioids, the usual initial dose is one tablet of 5 mg in 12 hourly intervals. Your doctor will prescribe the dose required to treat pain. However, tell your doctor if the dose you are taking does not control your pain.

Risk patients
If you have impaired kidney and/or liver function or if you have a low body weight your doctor may prescribe a lower starting dose.

Method and duration of administration
Oxycodon-HCl Accord 5 mg prolonged-release tablets
Swallow the prolonged-release tablets whole with a sufficient amount of liquid (½ glass of water) with or without food in the morning and in the evening following a fixed schedule (e.g. at 8 a.m. and 8 p.m.).
Oxycodon-HCl Accord 10 mg, 20 mg, 40 mg, 80 mg prolonged-release tablets
Swallow the prolonged-release tablets either whole or broken up with a sufficient amount of liquid (½ glass of water) with or without food in the morning and in the evening following a fixed schedule (e.g. at 8 a.m. and 8 p.m.).
The prolonged-release tablets must not be crushed or chewed as this leads to rapid oxycodone release due to the damage of the prolonged-release properties. The administration of chewed or crushed Oxycodon-HCl Accord leads to a rapid release and absorption of a potentially fatal dose of oxycodone (see section "If you take more Oxycodon-HCl Accord than you should").
Oxycodon-HCl Accord are for oral use only. In case of abusive injection (injection in a vein) the tablet excipients may lead to destruction (necrosis) of the local tissue, change of lung tissue (granulomas of the lung) or other serious, potentially fatal events.
Your doctor will adjust the dosage depending on the pain intensity and how you respond to the treatment. Take the number of prolonged-release tablets determined by your doctor twice daily.

Opening instruction for the blister package:
this medicinal product is packed in a child-resistant blister. You cannot press out the prolonged-release tablets through the blister package. Please observe the following opening instruction for the blister package:

1. Tear off a single dose along the perforation line of the blister package.
2. Hereby an unsealed area is accessible which is located at the position, where the perforation lines have crossed.

3. Pull at the unsealed "strap" to peel off the cover seal.

If you take more Oxycodon-HCl Accord than you should
If you have taken more Oxycodon-HCl Accord as prescribed you should inform your doctor or your local poison control center immediately. The following symptoms may occur: constricted pupils (miosis), depressed breathing (respiratory depression), skeletal muscle flaccidity and drop in blood pressure. In severe cases circulatory collapse, mental and motor inactivity (torpor), unconsciousness (coma), slowing of the heart rate and accumulation of water in the lungs (non-cardiogenic lung oedema) may occur; abuse of high doses of strong opioids such as oxycodone can be fatal. In no case you should expose yourself to situations requiring elevated concentration e.g. driving a car.

If you forget to take Oxycodon-HCl Accord
If you use a smaller dose of Oxycodon-HCl Accord than directed or you miss the intake of the tablets, pain relief will consequently be insufficient or cease altogether.
You can make up for a forgotten tablet if the next regular intake is not due for at least another 8 hours. You can then continue to take the tablets as directed.
You should also take the prolonged-release tablets if the time to the regular next intake is shorter, but postpone the next intake by 8 hours. In principle, you should not take Oxycodon-HCl Accord more than once every 8 hours.
Do not take a double dose to make up for a forgotten tablet.

If you stop taking Oxycodon-HCl Accord
Do not stop treatment without informing your doctor.
When a patient no longer requires therapy with Oxycodon-HCl Accord, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal.

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

4. Possible side effects

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

All medicines can cause allergic reactions, although serious allergic reactions are rare. **Tell your doctor immediately** if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body.

The most serious side effect is a condition where you breathe more slowly or weakly than expected (respiratory depression). **Tell your doctor immediately** if this happens to you

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

Other possible side effects

Very common (may affect more than 1 in 10 people)
- itchy skin
- Drowsiness (this is most likely when you start taking your tablets or when your dose is increased, but it should wear off after a few days).
- Dizziness,
- Headache
- feeling or being sick (this should normally wear off after a few days, however your doctor can prescribe an anti-sickness medicine if it continues to be a problem).

- constipation (your doctor can prescribe a laxative to overcome this problem)

Common (may affect up to 1 in 10 people)
- Dry mouth, loss of appetite, indigestion, abdominal pain or discomfort, diarrhoea.
- Confusion, depression, a feeling of unusual weakness, shaking, lack of energy, tiredness, anxiety, nervousness, difficulty in sleeping, abnormal thoughts or dreams.
- Difficulty in breathing or wheezing, shortness of breath, decreased cough reflex.
- Rash.
- Sweating.

Uncommon (may affect up to 1 in 100 people)
- Difficulty in swallowing, belching, hiccups, wind, a condition where the bowel does not work properly (ileus), inflammation of the stomach, changes in taste.
- A feeling of dizziness or 'spinning', hallucinations, mood changes, unpleasant or uncomfortable mood, a feeling of extreme happiness, restlessness, agitation, generally feeling unwell, loss of memory, difficulty in speaking, reduced sensitivity to pain or touch, tingling or numbness, seizures, fits or convulsions, blurred vision, fainting, unusual muscle stiffness or slackness, involuntary muscle contractions.
- Difficulty in passing urine, impotence, decreased sexual drive, low levels of sex hormones in the blood ('hypogonadism', seen in a blood test).
- Fast, irregular heart beat, flushing of the skin.
- Dehydration, thirst, chills, swelling of the hands, ankles or feet.
- Dry skin, severe flaking or peeling of the skin, hives (nettle rash).
- Redness of the face, reduction in size of the pupils in the eye, muscle spasm, high temperature.
- A need to take increasingly higher doses of the tablets to obtain the same level of pain relief (tolerance).
- Colicky abdominal pain or discomfort.
- A worsening of liver function tests (seen in a blood test).

Rare (May affect up to 1 in 1,000 people)
- Low blood pressure.
- A feeling of 'faintness' especially on standing up.
- Hives (nettle rash).

Frequency not known: (frequency cannot be estimated from the available data)
- increased sensitivity to pain
- Aggression
- Absence of menstrual periods.
- A blockage in the flow of bile from the liver (cholestasis). This can cause itchy skin, yellow skin, very dark urine and very pale stools.
- Long term use of Oxycodone during pregnancy may cause life-threatening withdrawal symptoms in the newborn. 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.

<u>You may see the remains of the tablets in your faeces. This should not affect how the tablets work.</u>

<u>Counteractive measures</u>
If you observe any of the above listed side effects your doctor usually will take appropriate measures. The side effect constipation may be prevented by fiber enriched diet and increased

drinking. If you are suffering from sickness or vomiting your doctor will prescribe you an appropriate medicine.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Oxycodon-HCl Accord

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/bottle and the carton after "EXP". The expiry date refers to the last day of that month.

Do not use this medicine if you notice deterioration of the tablets (broken or crushed) has occurred.

This medicinal product 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 of medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Oxycodon-HCl Accord contains

The active substance is oxycodone hydrochloride.
Each prolonged-release tablet contains 5 mg, 10 mg, 20 mg, 40 mg or 80 mg oxycodone hydrochloride equivalent to 4.5 mg, 9.0 mg, 17.9 mg, 36 mg or 72 mg oxycodone.

The other ingredients are:

Tablet core: Sugar spheres (contains sucrose, maize starch, starch hydrolysates and colour additivessucrose, maize starch), hypromellose, talc, ethylcellulose, Hydroxypropylcellulose, propylene glycol, carmellose sodium, microcrystalline cellulose, magnesium stearate [plant-based], colloidal anhydrous silica.
Tablet coating: Titanium dioxide (E 171), macrogol 3350, talc (5 mg, 20 mg).
Titanium dioxide (E 171), macrogol 3350, talc, red iron oxide (10 mg, 40 mg).
Macrogol 3350, talc, red iron oxide (80 mg).

What Oxycodon HCl Accord looks like and contents of the pack

Oxycodon-HCl Accord 5 mg Prolonged release Tablets are white to off-white, round, biconvex tablets.
Oxycodon-HCl Accord 10 mg Prolonged release Tablets are pink, oblong, biconvex tablets with break scores on both sides. The tablet can be divided into equal halves.
Oxycodon-HCl Accord 20 mg Prolonged release Tablets are white to off-white, oblong, biconvex Tablets with break scores on both sides. The tablet can be divided into equal halves.
Oxycodon-HCl Accord 40 mg Prolonged release Tablets are pale pink, oblong, biconvex tablets with break scores on both sides. The tablet can be divided into equal halves.

Oxycodon-HCl Accord 80 mg Prolonged release Tablets are red, oblong, biconvex tablets with break scores on both sides. The tablet can be divided into equal halves.

Pack sizes:
10, 14, 20, 28, 30, 50, 56, 60, 98, 100, 120 prolonged-release tablets in PVC/PE/PVDC-aluminium blister.
10, 20, 30, 50, 100 prolonged-release tablets in HDPE bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Accord Healthcare Limited,
Sage house, 319 Pinner road,
North Harrow, Middlesex, HA1 4HF
United Kingdom

Manufacturer

Accord Healthcare Limited,
Sage house, 319 Pinner road,
North Harrow,
Middlesex, HA1 4HF
United Kingdom

Develco Pharma GmbH
Grienmatt 27,
79650 Schopfheim,
Germany

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

Name of member state	Name of medicinal product
Ireland	Zomestine 5 mg 10 mg 20 mg 40 mg 80 mg prolonged-release tablets
Italy	Oxycodon Accord
Netherlands	Oxycodon-HCl Accord 5 mg 10 mg 20 mg 40 mg 80 mg tabletten met verlengde afgifte
United Kingdom	Zomestine 5 mg 10 mg 20 mg 40 mg 80 mg prolonged-release tablets
Poland	Accordeon 5 mg 10 mg 20 mg 40 mg 80 mg tabletki o przedłużonym uwalnianiu
Finland	Oxycodon-HCl Accord 5 mg 10 mg 20 mg 40 mg 80 mg depottabletit

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