Package leaflet: Information for the patient

Leveraxo 5 mg, 10 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg Prolonged-release Tablets

(oxycodone hydrochloride)

This medicine contains oxycodone which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

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 Leveraxo is and what it is used for

Leveraxo is a centrally acting, strong painkiller from the group of opioids.

This medicine has been prescribed to you for the treatment of severe pain in adults and adolescents aged 12 years and older, which can be adequately managed only with opioid analgesics. It contains the oxycodone which belongs to a class of medicines called opioids, which are 'pain relievers'.

This medicine has been prescribed to you and should not be given to anyone else.

Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your doctor or pharmacist should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you take Leveraxo

Do not take Leveraxo:
- if you are allergic to oxycodone or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from severely depressed breathing (respiratory depression) with too little oxygen in the blood (hypoxia) and/or too much carbon dioxide (hypercapnia) in the blood
- if you suffer from severe chronic obstructive lung disease, cor pulmonale (cardiac changes due to chronic overload of lung circulation) or acute, severe bronchial asthma
- if you suffer from intestinal paralysis (paralytic ileus).

Warnings and precautions
Talk to your doctor or pharmacist before taking Leveraxo if you:
- are older or debilitated
- have severely impaired lung, liver or kidney function (see section 3 'Risk patients')
- suffer from myxoedema (certain illnesses of the thyroid gland), or an impaired function of the thyroid gland
- have poor adrenal gland function (your adrenal gland is not working properly) for example Addison's disease
- suffer from toxic psychosis (e.g. alcohol)
- suffer from enlargement of the prostate (prostate hypertrophy)
- suffer from alcoholism or are undergoing alcohol withdrawal with symptoms such as shaking, feeling anxious or disoriented, seeing, hearing or feeling things that are not real (hallucinations)
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs,
- feel you need to take more of Leveraxo to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your doctor or pharmacist who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.
- suffer from known opioid-dependence
- suffer from inflammation of the pancreas (pancreatitis)
- suffer from diseases of the biliary tract
- suffer from inflammatory bowel disorders
- suffer from an obstruction of the intestine
- suffer from low blood pressure
- suffer from decreased blood volume (hypovolaemia)
- suffer from head injury
- suffer from epilepsy or have a seizure (fits) tendency
- take MAO inhibitors (for the treatment of depression).

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.

Pre- and post-operative pain
Do not use Leveraxo for acute post-operative pain because of the increased risk of dependency and developing serious breathing problems.
If you are going to have an operation, or have just had an operation, please tell the doctor at the hospital if you are taking Leveraxo. Your doctor may adjust your dose.

Tolerance, dependence and addiction

This medicine contains oxycodone, which is an opioid. It can cause dependence and/or addiction.

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 Leveraxo may lead to dependence, abuse and addictions, 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 Leveraxo:

- if you are or anyone in your family have ever been addicted to opioids, 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,

Taking this medicine regularly, particularly for a long time, can lead to addiction and may result in life-threatening overdose. If you have concern that you may become dependent on Leveraxo it is important that you consult your doctor. Your doctor or pharmacist should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your doctor or pharmacist about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your doctor or pharmacist will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

If you notice any of the following signs whilst taking Leveraxo, 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 Leveraxo).

<u>Sleep-related breathing disorders</u>
Leveraxo can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

<u>Long term treatment and abuse</u>
Leveraxo has primary dependence potential. When used for a long time tolerance to the effects may develop and progressively higher doses may be required to maintain pain control.

Chronic use of Leveraxo may lead to physical dependence and a withdrawal syndrome may occur upon abrupt cessation of therapy. When a patient no longer requires therapy with oxycodone hydrochloride, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal.

When used as directed in patients suffering from chronic pain the risk of developing physical or psychological dependence is markedly reduced and needs to be weighed against the potential benefit. Please discuss this with your doctor.

Leveraxo is for oral use only. In case of abusive injection (injection in a vein) the other tablet ingredients may lead to destruction (necrosis) of the local tissue, change of lung tissue (granulomas of the lung) or other serious, potentially lethal events.

Anti-doping warning
Athletes should be aware that this medicine may cause a positive reaction to "anti-doping tests". Use of Leveraxo as a doping agent may become a health hazard.

Children under 12 years of age
Leveraxo should not be used in children under 12 years of age because of safety and efficacy concerns.

Elderly patients
In elderly patients without impairment of kidney and/or liver function a dose adjustment is usually not necessary.

Other medicines and Leveraxo
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines:

- medicines that dampen the activity of the central nervous system, e.g.
  - sleeping pills or tranquillisers (sedatives, hypnotics)
  - other medicines that act on the nervous system (phenothiazines, neuroleptics, anaesthetics, antidepressants, muscle relaxants)
  - other opioids or alcohol can enhance the side effects of oxycodone, in particular depressed breathing (respiratory depression)
  - concomitant use with sedative medicines such as benzodiazepines, e.g. diazepam, or related medicines 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 Leveraxo 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.
- medicines with an anticholinergic effect, e.g.
  - other medicines that act against parasympathetic and cholinergic nerve fibres on the central nervous system (psychotropic medicines)
  - medicines used to treat allergies (antihistamines) or vomiting (antiemetics)
  - medicines used to treat Parkinson's disease can enhance certain side effects of oxycodone (e.g. constipation, dry mouth or urinary disturbances).
- inhibitors of CYP3A4, such as macrolide antibiotics (e.g. clarithromycin, erythromycin, telithromycin), azole antifungals (e.g. ketoconazole, voriconazole, itraconazole, posaconazole), protease inhibitors (e.g. boceprevir, ritonavir, indinavir, nelfinavir, saquinavir), cimetidine and grapefruit juice may cause a reduced clearance of oxycodone that could cause an increase of the

plasma concentrations of oxycodone. The influence of other medicines that can markedly affect the metabolism of oxycodone has not been investigated
- strong inhibitors of CYP2D6 (such as paroxetine, quinidine) may affect the elimination of oxycodone. The influence of other isoenzyme inhibitors that can markedly affect the metabolism of oxycodone is not known
- CYP3A4 inducers such as rifampicin, carbamazepine, phenytoin and St John´s Wort may induce the metabolism of oxycodone and cause an increased clearance of oxycodone that could cause a reduction of the plasma concentrations of oxycodone
- monoamine oxidase inhibitors (MAOIs) such as tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid
- in individuals a clinically relevant increase or decrease of blood clotting have been observed if anticoagulants of the coumarin type (medicinal products against blood clotting) are co-applied with Leveraxo.

Leveraxo with alcohol
Drinking alcohol whilst taking Leveraxo 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 are taking Leveraxo.

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
Do not take Leveraxo if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Leveraxo during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated(see section 4 ‘Possible side effects’). Use of oxycodone during delivery can cause breathing problems (respiratory depression) in the newborn.

Breast-feeding
Do not take Leveraxo while you are breastfeeding as oxycodone passes into breast milk and will affect your baby.

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. In these circumstances Leveraxo has moderate to major influence on the ability to drive and use machines.
With stable therapy, a general ban on driving a vehicle may be not necessary. In these circumstances Leveraxo has minor influence on the ability to drive and use machines. The treating physician must assess the individual situation. Please discuss with your doctor whether or under what conditions you can drive a vehicle.

Leveraxo contains sucrose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. This medicine also contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially ‘sodium-free’.

3. How to take Leveraxo

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 or pharmacist should have discussed with you, how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

For doses not realisable/practicable with this medicine, other strengths and medicines are available.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Leveraxo, 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 Leveraxo).

The recommended dose is

Adults and adolescents (aged 12 years and older)
The usual initial dose is 10 mg of oxycodone hydrochloride in 12 hourly intervals. Some patients may benefit from a starting dose of 5 mg to minimise the incidence of adverse reactions.

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 Leveraxo according to a fixed schedule need rapidly acting painkillers as rescue medication to control breakthrough pain. Leveraxo is 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.

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.

Route and method of administration
Oral use. It is not recommended to take Leveraxo with alcoholic beverages.

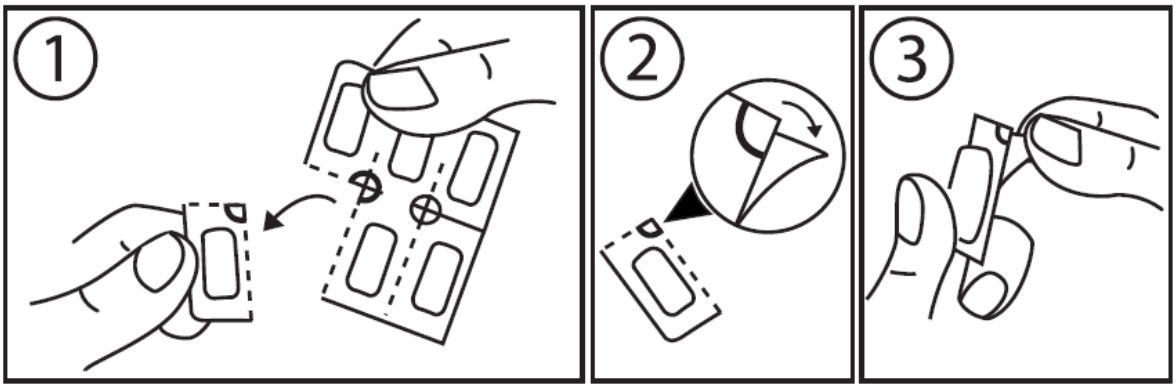
Swallow the prolonged-release tablets with a sufficient amount of liquid (½ glass of water) with or without food in the morning and in the evening following a fixed schedule (e.g. at 8 a.m. and 8 p.m.).

Leveraxo 5 mg prolonged-release tablets must be swallowed whole and must not be divided, broken, chewed or crushed as this leads to rapid oxycodone release due to the damage of the prolonged-release properties. The administration of divided, broken, chewed or crushed Leveraxo leads to a rapid release and absorption of a potentially fatal dose of oxycodone (see section ‘If you take more Leveraxo than you should’).

Leveraxo 10 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg prolonged-release tablets can be divided into equal doses. However, do not chew or crush the tablet as this leads to rapid oxycodone release due to the damage of the prolonged-release properties. The administration of chewed or crushed Leveraxo leads to a rapid release and absorption of a potentially fatal dose of oxycodone (see section

'If you take more Leveraxo than you should').

Opening instructions for the blister
This medicine is packed in a child-resistant perforated unit dose blister. You cannot press out the prolonged-release tablets through the blister. Please observe the following opening instruction for the blister:



1. Tear off a single dose along the perforation line of the blister.
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.

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.

If you take more Leveraxo than you should
If you have taken more Leveraxo as prescribed you should inform your doctor or your local poison control centre **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.

An overdose may result in a brain disorder known as toxic leukoencephalopathy.

If you forget to take Leveraxo
If you use a smaller dose of Leveraxo than directed or you miss the intake of Leveraxo, pain relief will consequently be insufficient or cease altogether.

You can make up for a forgotten dose if the next regular intake is not due for at least another 8 hours. You can then continue to take your recommended dose as directed.

You should also take Leveraxo if the time to the regular next intake is shorter, but postpone the next intake by 8 hours. In principle, you should not take Leveraxo more than once every 8 hours.

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

If you stop taking Leveraxo
Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your doctor or pharmacist first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms

such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine. A withdrawal syndrome may occur upon abrupt cessation of therapy. For symptoms of the withdrawal syndrome see section 4.

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.

If you experience any of the following side effects, stop taking Leveraxo and contact your doctor immediately:
- depressed breathing. This is the most significant risk induced by opioids and is most likely to occur in elderly or debilitated patients. As a consequence, in predisposed patients opioids can cause severe drops in blood pressure
- constricted pupils, bronchial spasms and spasms in smooth muscles or suppression of the cough reflex
- serious allergic reaction with symptoms that include feeling dizzy or faint, rash, itchy skin, swelling of the face, lips, tongue or throat that may cause difficulty breathing or swallowing
- obstruction of the gut (ileus) with symptoms such as persistent constipation, abdominal swelling and vomiting
- blockage of the bile duct (cholestasis) with symptoms such as abdominal pain, tenderness and swelling, vomiting
- inability to pass urine or empty the bladder (urinary retention)
- black tar-like stools

Other possible side effects:

Very common (may affect more than 1 in 10 people):
- sedation (tiredness to drowsiness), dizziness, headache
- constipation, feeling or being sick
- itching.

Common (may affect up to 1 in 10 people):
- reduced appetite or loss of appetite
- altered mood and personality changes (anxiety), confusional state, depression
- sleeplessness, nervousness, abnormal thinking
- lack of energy or enthusiasm (lethargy)
- trembling (tremor)
- depressed breathing (dyspnoea)
- dry mouth
- restlessness
- hyperactivity
- bellyache, diarrhoea, hiccups, upset stomach (dyspepsia)
- skin disorders such as rash
- pain, burning or discomfort when urinating
- frequent or urgent urination
- sweating including abnormally increased sweating
- powerlessness.

Uncommon (may affect up to 1 in 100 people):
- hypersensitivity
- lack of water in the body (dehydration)
- agitation, emotional lability
- euphoric mood, seeing, hearing or feeling things that are not real (hallucinations)
- disturbances of sexual function (reduced sexual desire and erectile dysfunction)
- reduced levels of sex hormones (hypogonadism), which may cause changes to sperm production in males or the menstrual cycle in females
- withdrawal symptoms like fast or irregular heart beat (palpitations)
- loss of memory (amnesia), convulsion
- impaired hearing
- increased heart rate
- increased muscle tone, involuntary muscle contractions, reduced coordination
- reduced sense of touch (hypaesthesia)
- speech disorders, cough
- fainting, paraesthesia, change in taste, migraine
- impaired concentration
- visual impairment, constriction of the pupil
- vertigo
- injuries from accidents
- widening of the blood vessels (vasodilatation)
- difficulty swallowing (dysphagia), flatulence, burping
- ulcers or inflammation of the mouth, tongue or lips
- increased liver enzymes
- dry skin
- chills, general discomfort, thirst
- drug tolerance
- drug dependence and addiction (see section "How do I know if I am addicted?").
- swelling of any organ or tissue due to accumulation of excess fluid (oedema).

Rare (may affect up to 1 in 1,000 people):
- decreased blood pressure (hypotension), which may cause dizziness when standing up (orthostatic hypotension)
- urticaria
- blisters that develop on the lips or around the mouth (herpes simplex)
- increased appetite
- black tarry stools
- tooth disorder
- bleeding gums
- increase or decrease in weight.

Frequency not known (cannot be estimated from the available data):
- anaphylactic responses
- aggression
- increased sensitivity to pain (hyperalgesia)
- dental caries
- pain in the abdomen, possibly with nausea and vomiting, caused by a blockage of the bile duct (biliary colic)
- a problem affecting a valve in the intestines that may cause severe upper abdominal pain (sphincter of Oddi dysfunction)
- absence of menstrual bleeding (amenorrhoea)
- long term use of Oxycodone 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.
- sleep apnoea (breathing pauses during sleep)

Drug Withdrawal
When you stop taking Leveraxo, you may experience drug withdrawal symptoms, which include restlessness, increased production of tears, runny nose, yawning, shaking, shivering, sweating, chills, muscle pain, abnormal dilatation of the pupil and sensation of irregular and forceful heartbeat. Other symptoms may also develop, including: irritability, agitation, anxiety, feeling your heartbeat (palpitations), backache, joint pain, weakness, belly cramps, sleeplessness, feeling or being sick, lack of appetite, vomiting, diarrhoea, or increased blood pressure, breathing rate or heart rate.

How do I know if I am addicted?
If you notice any of the following signs whilst taking Leveraxo, it could be a sign that you have become addicted:
- you need to take the medicine for longer than advised by your doctor or pharmacist
- you feel you need to use more than the recommended dose
- you are using the medicine for reasons other than prescribed
- when you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your doctor or pharmacist.

Counteractive measures
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 fibre 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 Yellow Card Scheme at 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 Leveraxo

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 or label, and the carton after “EXP”. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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 Leveraxo contains

The active substance is oxycodone hydrochloride.

- Leveraxo 5 mg prolonged-release tablets: Each prolonged-release tablet contains 5 mg oxycodone hydrochloride as active substance, equivalent to 4.5 mg oxycodone.
  Other ingredients are the tablet core consisting of sugar spheres (sucrose, maize starch), hypromellose, talc, ethyl cellulose, hydroxypropylcellulose, propylene glycol, carmellose sodium, cellulose microcrystalline, magnesium stearate (Ph. Eur.), silica colloidal anhydrous and the tablet coating consisting of polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc.

- Leveraxo 10 mg prolonged-release tablets: Each prolonged-release tablet contains 10 mg oxycodone hydrochloride as active substance, equivalent to 9 mg oxycodone.
  Other ingredients are the tablet core consisting of sugar spheres (sucrose, maize starch), hypromellose, talc, ethyl cellulose, hydroxypropylcellulose, propylene glycol, carmellose sodium, cellulose microcrystalline, magnesium stearate (Ph. Eur.), silica colloidal anhydrous and the tablet coating consisting of polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, iron oxide red (E172), talc.

- Leveraxo 20 mg prolonged-release tablets: Each prolonged-release tablet contains 20 mg oxycodone hydrochloride as active substance, equivalent to 17.9 mg oxycodone.
  Other ingredients are the tablet core consisting of sugar spheres (sucrose, maize starch), hypromellose, talc, ethyl cellulose, hydroxypropylcellulose, propylene glycol, carmellose sodium, cellulose microcrystalline, magnesium stearate (Ph. Eur.), silica colloidal anhydrous and the tablet coating consisting of polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc.

- Leveraxo 30 mg prolonged-release tablets: Each prolonged-release tablet contains 30 mg oxycodone hydrochloride as active substance, equivalent to 26.9 mg oxycodone.
  Other ingredients are the tablet core consisting of sugar spheres (sucrose, maize starch), hypromellose, talc, ethyl cellulose, hydroxypropylcellulose, propylene glycol, carmellose sodium, cellulose microcrystalline, magnesium stearate (Ph. Eur.), silica colloidal anhydrous and the tablet coating consisting of polyvinyl alcohol, titanium dioxide (E171), iron oxide yellow (E172), macrogol 3350, talc.

- Leveraxo 40 mg prolonged-release tablets: Each prolonged-release tablet contains 40 mg oxycodone hydrochloride as active substance, equivalent to 36 mg oxycodone.
  Other ingredients are the tablet core consisting of sugar spheres (sucrose, maize starch), hypromellose, talc, ethyl cellulose, hydroxypropylcellulose, propylene glycol, carmellose sodium, cellulose microcrystalline, magnesium stearate (Ph. Eur.), silica colloidal anhydrous and the tablet coating consisting of polyvinyl alcohol, titanium dioxide (E171), iron oxide red (E172), macrogol 3350, talc.

- Leveraxo 60 mg prolonged-release tablets: Each prolonged-release tablet contains 60 mg oxycodone hydrochloride as active substance, equivalent to 53.8 mg oxycodone.
  Other ingredients are the tablet core consisting of sugar spheres (sucrose, maize starch), hypromellose, talc, ethyl cellulose, hydroxypropylcellulose, propylene glycol, carmellose sodium, cellulose microcrystalline, magnesium stearate (Ph. Eur.), silica colloidal anhydrous and the tablet coating consisting of polyvinyl alcohol, macrogol 3350, iron oxide yellow (E172), talc.

- Leveraxo 80 mg prolonged-release tablets: Each prolonged-release tablet contains 80 mg oxycodone hydrochloride as active substance, equivalent to 72 mg oxycodone.
  Other ingredients are the tablet core consisting of sugar spheres (sucrose, maize starch), hypromellose, talc, ethyl cellulose, hydroxypropylcellulose, propylene glycol, carmellose sodium, cellulose microcrystalline, magnesium stearate (Ph. Eur.), silica colloidal anhydrous and the tablet coating consisting of polyvinyl alcohol, iron oxide red (E172), macrogol 3350, talc.

What Leveraxo looks like and contents of the pack

Leveraxo 5 mg prolonged-release tablets
White to off-white, round, biconvex tablet. The height of the tablet is between 3.3 and 4.3 mm, the diameter is 5.2 mm.

Leveraxo 10 mg prolonged-release tablets
Pink, oblong, biconvex tablet with break scores on both sides. The height of the tablet is between 4 and 5 mm, the width is 4.8 mm and the length is 10.3 mm.

Leveraxo 20 mg prolonged-release tablets
White to off-white, oblong, biconvex tablet with break scores on both sides. The height of the tablet is between 3.3 and 4.3 mm, the width is 4.8 mm and the length is 10.3 mm.

Leveraxo 30 mg prolonged-release tablets
Yellow, oblong, biconvex tablet with break scores on both sides. The height of the tablet is between 3.8 and 4.8 mm, the width is 5.3 mm and the length is 11.3 mm.

Leveraxo 40 mg prolonged-release tablets
Pink, oblong, biconvex tablet with break scores on both sides. The height of the tablet is between 4.8 and 5.8 mm, the width is 5.8 mm and the length is 12.4 mm.

Leveraxo 60 mg prolonged-release tablets
Dark yellow, oblong, biconvex tablet with break scores on both sides. The height of the tablet is between 5 and 6 mm, the width is 6.8 mm and the length is 14.5 mm.

Leveraxo 80 mg prolonged-release tablets
Red, oblong, biconvex tablet with break scores on both sides. The height of the tablet is between 5.8 and 6.8 mm, the width is 7.4 mm and the length is 15.5 mm.

Pack sizes:
10x1, 14x1, 20x1, 28x1, 30x1, 50x1, 56x1, 60x1, 98x1, 100x1 prolonged-release tablets in child resistant, white opaque perforated unit dose blister.
10, 20, 30, 50, 100 prolonged-release tablets in bottles with child-resistant closure.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer
Develco Pharma GmbH, Grienmatt 27, 79650 Schopfheim, Germany

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