PACKAGE LEAFLET: INFORMATION FOR THE USER

Reltebon® 20mg Prolonged-release Tablets

(oxycodone hydrochloride)

This medicine contains Oxycodone hydrochloride 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.
- The name of your medicine is Reltebon® 20mg Prolonged-release Tablets but will be referred to as Reltebon throughout the remainder of this leaflet.
- Reltebon is also available in other strengths.

What is in this leaflet

1. WHAT RELTEBON IS AND WHAT IT IS USED FOR

This medicine has been prescribed for you to relieve severe pain, which can only be adequately managed with opioid analgesics in adults and adolescents 12 years of age and older. It contains oxycodone hydrochloride, which is a centrally acting, strong painkiller which belongs to a class of medicines called opioids.
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 should have explained how long you will be taking it for, when it is appropriate to stop and how to do this safely.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RELTEBON

Do not take Reltebon 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 severe 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 **increased carbon dioxide levels in the blood**. Symptoms may include dizziness, drowsiness, fatigue, shortness of breath and headache
- have **moderate to severe liver problems**. If you have other long-term liver problems you should only take these tablets if recommended by your doctor
- have ongoing problems with **constipation.**

Warnings and precautions
Talk to your doctor or pharmacist before taking this medicine if you:
- are elderly or weakened
- have an under-active thyroid gland (hypothyroidism), as you may need a lower dose
- have myxoedema (a thyroid disorder with dryness, coldness and swelling ('puffiness') of the skin affecting the face and limbs)
- know you are suffering from a brain injury or tumour, or you have a head injury, severe headache or feel sick as this may indicate that the pressure in your skull is increased
- have low blood pressure (hypotension)
- have low blood volume (hypovolaemia), this can occur due to severe external or internal bleeding, severe burns, excessive sweating, severe diarrhoea or vomiting
- feel very lightheaded or faint
- have a mental disorder following use of certain medicines (toxic psychosis)
- have inflammation of the pancreas (which may cause severe pain in the abdomen and back)
- have colicky abdominal pain or discomfort
- have problems with your gall bladder or bile duct
- have inflammatory bowel disease
- have an enlarged prostate gland, which causes difficulty in passing urine (in men)
- 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
- have severely impaired lung function. Symptoms may include breathlessness and coughing
- have long term pain unrelated to cancer
- have a condition where your breathing stops for short periods whilst you are asleep, known as sleep apnoea
- have kidney or liver problems
- have recently had abdominal surgery.

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.

Tolerance, dependence and addiction
Repeated use of opioid painkillers can result in the drug being less effective (you become accustomed to it, known as tolerance).
Taking this medicine regularly, particularly for a long time, can lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use. Your doctor should have explained how long you will be taking it for, when it is appropriate to stop and how to do this safely.

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 to Reltebon if you:
- or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction")
- are a smoker
- have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses
- 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 Reltebon to get the same level of pain relief, as this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Talk to your doctor who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

See section 4 'How do I know if I am addicted?' for signs that you may have become dependent or addicted.

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

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.

Do not inject Reltebon. This can cause serious side effects including tissue death at the site of injection, infection, inflammation of the lungs and damage to the heart which may be fatal.

If you are going to have an operation, or have just had an operation, please tell the doctor at the hospital that you are taking these tablets.
Your doctor may adjust your dose. Reltebon is not recommended for use before an operation or in the 12-24 hours after an operation.

You may experience hormonal changes while taking these tablets. Your doctor may want to monitor these changes.

Sleep-related breathing disorders
Reltebon 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.

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

Other medicines and Reltebon
Taking Reltebon at the same time as other medicines that slow down the central nervous system can cause slow or difficulty breathing (respiratory depression), severe sleepiness, loss of consciousness and death.
These medicines include:
- other medicines used to treat pain known as opioids (such as codeine or morphine)
- other medicines used to treat epilepsy (gabapentinoids) such as pregabalin
- medicines used to treat anxiety
- medicines used to make you feel sleepy (such as benzodiazepines)
- medicines used to treat psychiatric or mental disorders (such as phenothiazines)
- anaesthetics
- muscle relaxants
- medicines used to treat high blood pressure
- a type of medicine used to treat depression known as monoamine oxidase inhibitors (MAOIs), such as tranylcypromine, phenelzine and isocarboxazid. You should not take Reltebon if you are currently taking this type of medicine, or have taken this medicine in the last two weeks.

Because of this, your doctor will only prescribe Reltebon where there are no other treatment options, and only in small doses for short periods of time. If you or your friends, family or caregivers notice that you are having difficulty breathing or that you have become very sleepy or lost consciousness you (or they) should inform your doctor immediately.

Concomitant use of Reltebon 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 Reltebon 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.

Taking Reltebon with medicines used to treat depression known as Selective Serotonin Re-uptake Inhibitors (SSRIs) or Serotonin Norepinephrine Re-uptake Inhibitors (SNRIs) can cause a condition known as serotonin toxicity. The risk of side effects increases, if you use these 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, as they may reduce your dose of Reltebon.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Tell your doctor or pharmacist if you are taking any of the following medicines, as they may need to adjust your dose:
- a type of medicine used to treat depression known as tricyclic antidepressants, such as amitriptyline, clomipramine, imipramine, lofepramine or nortriptyline
- medicines used to treat allergies such as cetirizine, fexofenadine or chlorphenamine
- medicines used to treat Parkinson's disease
- antibiotics such as clarithromycin, erythromycin or telithromycin
- antifungal medicines such as ketoconazole, voriconazole, itraconazole, and posaconazole
- medicines used to treat HIV known as protease inhibitors, such as boceprevir, ritonavir, indinavir, nelfinavir and saquinavir
- cimetidine, a medicine used to treat stomach ulcers
- rifampicin, a medicine used to treat tuberculosis
- medicines used to treat seizures, fits or convulsions such as carbamazepine and phenytoin
- a herbal remedy used to treat depression known as St John's Wort (also known as *Hypericum perforatum*)
- quinidine, a medicine used to treat an irregular heartbeat.

Reltebon with food, drink and alcohol
You **should not drink alcohol** while you are taking Reltebon. Drinking alcohol whilst taking Reltebon may make you feel sleepier or increase the risk of serious side effects such as shallow breathing with a risk of stopping breathing, and loss of consciousness.

Grapefruit juice can inhibit the metabolism of oxycodone which will increase its effect. Therefore you should avoid drinking grapefruit juice while taking Reltebon.

Pregnancy and breast-feeding
If you are pregnant or breastfeeding, 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 Reltebon if you are pregnant or think you might be pregnant unless you have discussed this with your doctor and the benefits of treatment are considered to outweigh the potential harm to the baby. If you take Reltebon during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

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

Driving and using machines
This medicine may cause a number of side effects such as drowsiness or dizziness which could affect your ability to drive or use machinery (see section 4 'Possible side effects' for a full list of side effects). These are usually most noticeable when you first start taking the tablets, or when changing to a higher dose. If you are affected you should not drive or use machinery.
- 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.

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

3. HOW TO TAKE RELTEBON

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from taking Reltebon, 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 Reltebon'). They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

Adults and adolescents over 12 years of age
The recommended initial dose is 5 or 10mg oxycodone hydrochloride, in 12 hourly intervals. However, your doctor will prescribe the dose required to treat pain.

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 Reltebon according to a fixed schedule need rapidly acting painkillers as rescue medication to control breakthrough pain. Reltebon is not intended for the treatment of breakthrough pain.

For the treatment of non cancer pain, a daily dose of 40mg of oxycodone hydrochloride (20mg given twice a day) is generally sufficient, but higher dosages may be necessary. Patients with cancer pain usually require dosages from 80 to 120mg of oxycodone hydrochloride which may be increased up to 400mg 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.

Kidney/liver impairment or low body weight
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.

Swallow your tablets whole with water. **Do not crush, dissolve or chew them.**

Reltebon tablets are designed to work properly over 12 hours when swallowed whole. If a tablet is broken, crushed, dissolved or chewed, the entire 12-hour dose may be absorbed rapidly into your body. This can be dangerous, causing serious problems such as an overdose, which may be fatal.

You should take your tablets every 12 hours. For instance, if you take a tablet at 8 o'clock in the morning, you should take your next tablet at 8 o'clock in the evening.

You must only take the tablets by mouth. The tablets should never be crushed or injected as this may lead to serious side effects, which may be fatal (see section 2 'Warnings and precautions').

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 Reltebon than you should
If you have taken more Reltebon than prescribed, or if someone accidentally swallows your capsules, you should inform your doctor or your local poison control centre **immediately**. The following symptoms may occur: constricted pupils, depressed breathing, skeletal muscle flaccidity, drowsiness and drop in blood pressure. In severe cases, a brain disorder (known as toxic leukoencephalopathy), circulatory collapse, mental and motor inactivity, unconsciousness, slowing of the heart rate, accumulation of water in the lungs, low blood pressure and death may occur; abuse of high doses of strong opioids such as oxycodone can be fatal. In no case should you expose yourself to situations requiring elevated concentration e.g. driving a car.

If you forget to take Reltebon
If you use a smaller dose of Reltebon 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 Reltebon more than once every 8 hours.
Do not take a double dose to make up for a forgotten tablet.

If you stop taking Reltebon
Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your doctor 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.

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 Reltebon and contact your doctor immediately.

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. These may be signs of a serious allergic reaction.

The most serious side effect is a condition where you breathe more slowly or weakly than usual (respiratory depression) and can lead to severe sleepiness and loss of consciousness. This side effect may affect up to 1 in 100 people and is more likely to occur when taking certain other medicines (see section 2 'Other medicines and Reltebon'). **Tell your doctor immediately** if this happens to you. You may wish to ask your friends, family or caregivers to monitor you for these signs and symptoms.

Other possible side effects
Very common (may affect more than 1 in 10 people):
- 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
- constipation (your doctor can prescribe a laxative to overcome this problem)
- 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)
- itchy skin.

Common (may affect up to 1 in 10 people):
- confusion, depression, 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
- dry mouth, abdominal pain or discomfort, diarrhoea, indigestion, loss of appetite
- skin disorders such as rash, increased sensitivity to light (photosensitivity), in isolated cases itchy or scaly rash, excessive sweating
- urinary disorders (frequent urination).

Uncommon (may affect up to 1 in 100 people):
- withdrawal symptoms (see 'Drug withdrawal')
- difficulty in swallowing, belching, wind, hiccups, a condition where the bowel does not work properly (ileus), inflammation of the stomach, changes in taste or unpleasant taste
- dehydration, thirst, chills, swelling of the hands, ankles or feet
- depersonalisation, a feeling of extreme happiness, hallucinations, abnormally acute sense of hearing, a feeling of dizziness or spinning (vertigo), decreased sex drive, disorientation, mood changes, restlessness, agitation, unpleasant or uncomfortable mood
- generally feeling unwell, loss of memory, difficulty in speaking, reduced sensitivity to pain or touch, tingling or numbness, seizures, fits or convulsions, blurred or impaired vision, unusual muscle stiffness or slackness, involuntary muscle contractions or spasms, coordination disturbances
- abnormal production of antidiuretic hormone
- fast, irregular heartbeat, palpitations, a feeling of lightheadedness, dizziness or fainting, flushing of the skin
- widening of the blood vessels
- increased coughing, sore throat, runny nose, voice changes, difficulty breathing
- oral ulcers, inflammation of the gums, inflamed mouth
- dry skin, severe flaking or peeling of the skin
- difficulty or pain in passing urine
- decreased sexual drive, impotence, low levels of sex hormones in the blood ('hypogonadism', seen in a blood test)
- injuries due to accidents
- pain (e.g. chest pain), migraine
- redness of the face, changes in tear secretion, constriction of the pupil, 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):
- lymph node disease
- low blood pressure, feeling faint, especially on standing up
- gum bleeding, increased appetite, tarry stool, tooth staining
- herpes simplex (disorder of the skin and mucosa)
- raised, itchy rash (hives)
- blood in the urine
- increase or decrease in body weight, cellulitis.

Not known (frequency cannot be estimated from the available data):
- dependence and addiction (see section 'How do I know if I am addicted?')
- severe hypersensitivity reactions (anaphylactic reactions)
- aggression
- an increased sensitivity to pain
- 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
- sleep apnoea (breathing pauses during sleeping)
- tooth decay
- absence of menstrual periods
- 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.
- a problem affecting a valve in the intestines that may cause severe upper abdominal pain (sphincter of Oddi dysfunction).

Drug Withdrawal
When you stop taking Reltebon, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?
If you notice any of the following signs whilst taking Reltebon, 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 feel you need to use 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, it is important you talk 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 Reltebon').

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any 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 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 RELTEBON

- Keep out of the sight and reach of children. Accidental overdose by a child is dangerous and may be fatal. 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 store above 25ºC.
- Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- If your medicine becomes discoloured or shows any sign of deterioration, return it to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Reltebon contains
Each prolonged-release tablet contains 20mg oxycodone hydrochloride corresponding to 18mg of oxycodone.

The other ingredients are:
Tablet core: lactose monohydrate, hypromellose, povidone K30, stearic acid, magnesium stearate and colloidal anhydrous silica.
Tablet coating: polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc and red iron oxide (E172).

What Reltebon looks like and contents of the pack
Reltebon 20mg Prolonged-release Tablets are pink, round, biconvex tablets, 7mm in diameter, with 'OX 20' debossed on one side and plain on the reverse.

Reltebon is available in blister packs of 30 or 56 tablets.

Manufactured by
Generis Farmaceutica, S.A., Rua Joao de Deus 19, 2700-487 Amadora, Portugal.

PUREN Pharma GmbH & Co. KG, Willy-Brandt-Allee 2, 81829 Munchen, Germany.

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