Package leaflet: Information for the patient

Dancex SR 5 mg Prolonged-release tablets
Dancex SR 10 mg Prolonged-release tablets
Dancex SR 20 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

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1 What Dancex SR is and what it is used for

Dancex SR contains the active substance oxycodone hydrochloride which is a centrally acting, strong painkiller of the group of opioids.

Dancex SR is used in adults and adolescents aged 12 years and older to treat severe pain, which can be adequately managed only with opioid analgesics.

2 What you need to know before you take Dancex SR

Do not take Dancex SR 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 severely depressed breathing (respiratory depression), severe chronic obstructive lung disease, or severe bronchial asthma. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected.
- have elevated carbon dioxide blood levels
- have a heart problem after long-term lung disease (cor pulmonale)
- suffer from intestinal paralysis (paralytic ileus). Signs may be that your stomach empties more slowly than it should (delayed gastric emptying) or you have severe pain in your abdomen.

Warnings and precautions
Talk to your doctor or pharmacist before taking Dancex SR if you
- are elderly or weakened
- have severely impaired lung function
- have liver or kidney problems
- have a thyroid disorder with dryness, coldness and swelling of the skin affecting the face and limbs (myxoedema)
- have impaired function of the thyroid gland
- suffer from adrenal insufficiency which may cause symptoms including weakness, weight loss, dizziness, feeling or being sick (Addison's disease)
- have an enlarged prostate gland which causes difficulty in passing urine (in men)
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating upon stopping taking alcohol or drugs
- or anyone in your family has ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction")
- are a smoker
- have 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
- have a mental disorder as a result of poisoning, e.g. with alcohol (toxic psychosis)
- have inflammation of the pancreas which causes severe pain in the abdomen and back
- have problems with your gall bladder or bile duct
- have an obstructive or inflammatory bowel disease
- have a head injury, severe headache or feel sick as this may indicate that the pressure in your brain is increased
- have low blood pressure
- have low blood volume (hypovolaemia); this can happen with severe bleeding, severe burns, excessive sweating, severe diarrhoea or vomiting
- have epilepsy or a tendency to fits/convulsions
- are taking a type of medicine known as monoamine oxidase (MAO) inhibitors, for the treatment of depression or Parkinson's disease, or have taken them in the last 2 weeks
- are going to have an operation or had an abdominal surgery most recently.

Please talk to your doctor if any of these apply to you or if any of these conditions applied to you in the past.

Dancex SR may cause dependency. When used for a long time, tolerance to the effects may occur and progressively higher doses may be required to maintain pain control.

Chronic use of Dancex SR may lead to physical dependence and a withdrawal syndrome may occur upon abrupt cessation (see section 3. "If you stop taking Dancex SR"). Withdrawal symptoms may include yawning, dilation of the pupil of the eye, abnormal or excessive secretion of tears, running nose, trembling or shaking, increased sweating, anxiety, agitation, fits, sleeplessness and muscle pain.

An increased sensitivity to pain (hyperalgesia) that will not respond to a further dose increase of oxycodone may occur, particularly at high doses. An oxycodone dose reduction or change to an alternative opioid may be required.

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

The prolonged-release tablets should be used with particular care in patients with a history of or present alcohol and drug abuse.

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.

Sleep-related breathing disorders
Dancex SR 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.

You may see residue of the tablet in your stool.
Do not worry, as the active substance oxycodone hydrochloride has been released earlier while the tablet passed through the gastric system and have started to be effective in your body.

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

Children
Oxycodone prolonged-release tablets have not been studied in children under 12 years of age. Therefore, safety and efficacy have not been demonstrated and use of Dancex SR is not recommended in children under 12 years.

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

Concomitant use of Dancex SR and medicines which affect the way the brain works (e.g. sedative medicines such as benzodiazepines or related medicines, see below) 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 Dancex SR 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.

Medicines that affect the way the brain works include:
- other strong pain killers (opioids)
- sleeping pills and tranquillisers (sedative medicines such as benzodiazepines)
- medicines to treat depression, such as paroxetine
- medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics)
- medicines to treat psychiatric or mental disorders (antipsychotics)
- medicines used to treat Parkinson's disease.

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.

Further interactions may occur with:
- certain medicines to prevent your blood clotting or to help thin your blood (known as coumarin anticoagulants, for example warfarin or phenprocoumon). Dancex SR may influence their effects.
- muscle relaxants
- certain antibiotics (e.g. clarithromycin, erythromycin, telithromycin or rifampicin)
- certain medicines to treat fungal infections (e.g. ketoconazole, voriconazole, itraconazole or posaconazole)
- certain medicines to treat HIV infection (e.g. boceprevir, ritonavir, indinavir, nelfinavir or saquinavir)
- cimetidine, a medicine to treat heartburn
- carbamazepine (a medicine to treat seizures or convulsions/fits and certain pain conditions)
- phenytoin, a medicine to treat seizures
- St. John's wort, a medicine to treat depression
- quinidine (a medicine to treat a fast heartbeat)
- monoamine oxidase inhibitors, or if you have taken this type of medicine in the last two weeks (see section 2 'Warnings and precautions').

Taking Dancex SR with food, drink and alcohol
Drinking alcohol whilst taking Dancex SR 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 Dancex SR.

Drinking grapefruit juice whilst taking Dancex SR may increase the risk for side effects. You should avoid drinking grapefruit juice during treatment with Dancex SR.

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**

You should not take Dancex SR during pregnancy.
There are limited data from the use of oxycodone in pregnant women.
Oxycodone crosses the placenta into the blood circulation of the baby.
Prolonged use of oxycodone during pregnancy can cause withdrawal symptoms in newborns. Use of oxycodone during childbirth can cause breathing problems (respiratory depression) in the newborn.

- **Breast-feeding**

You should not use Dancex SR when you are breast-feeding as the active substance oxycodone may pass into breast milk and cause drowsiness (sedation) or breathing problems (respiratory depression) in the suckling child.

Driving and using machines
Dancex SR may impair the ability to drive or operate machinery.
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.

Dancex SR contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3 How to take Dancex SR

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

For dose adjustment other strengths of this medicine may be available.

The recommended dose is

Dancex SR 5 mg
Adults and adolescents (12 years of age and older)
The usual initial dose is two prolonged-release tablets (10 mg of oxycodone hydrochloride) at 12-hourly intervals. Your doctor will prescribe the dose required to treat your pain.

Dancex SR 10 mg
Adults and adolescents (12 years of age and older)
The usual initial dose is one prolonged-release tablet (10 mg of oxycodone hydrochloride) at 12-hourly intervals. Your doctor will prescribe the dose required to treat your pain.

Dancex SR 20 mg
Adults and adolescents (12 years of age and older)
The usual initial dose is 10 mg of oxycodone hydrochloride at 12-hourly intervals. Your doctor will prescribe the dose required to treat your 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 dose. Patients who have already taken opioids can start treatment with higher doses taking into account their experience with opioid treatment.

Some patients who receive Dancex SR prolonged-release tablets according to a fixed schedule need rapidly acting painkillers as rescue medication to control breakthrough pain. Dancex SR 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 doses may be necessary.
Patients with cancer pain usually require daily doses 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

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to decide whether treatment should be continued.

Patients with impaired kidney and/or liver function
Your doctor may prescribe a lower starting dose.

Other risk patients
If you have a low body weight or metabolise medicines at slower rates, your doctor may prescribe a lower starting dose.

Method of administration
For oral use only.

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.).

The prolonged-release tablets must not be divided, broken, crushed or chewed as this leads to rapid oxycodone release due to the damage of the prolonged-release properties. The administration of broken, chewed or crushed tablets leads to a rapid release and absorption of a potentially fatal dose of the active substance oxycodone (see section "If you take more Dancex SR than you should").

Dancex SR is 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 dose 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 Dancex SR than you should
If you have taken more Dancex SR than prescribed you should inform your doctor or your local poison control center immediately.

Signs of an overdose may be:
- narrowed pupils
- breathing more slowly or weakly (respiratory depression)
- sleepiness progressing up to loss of consciousness
- decreased muscle tone
- slowed pulse rate
- drop in blood pressure.

In severe cases, loss of consciousness (coma), water retention in the lung and circulatory collapse may occur, which may be fatal.

Never engage in situations which require a high degree of concentration, such as driving.

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

If you have forgotten to take a dose, please follow the instructions below:
- If the next regular dose was scheduled more than 8 hours later: Take the forgotten dose immediately and continue with your usual dosing schedule.
- If your next usual dose is due in less than 8 hours: Take the forgotten dose and wait another 8 hours before taking your next dose. Try to get back to your normal dosing schedule.

Do not take more than one dose within any 8-hour period.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Dancex SR
Do not stop treatment without informing your doctor.

If you no longer require therapy with Dancex SR, 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.

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. The side effect constipation may be countered by preventive measures (such as drinking plenty of fluids, nutrition rich in fibre). If you experience nausea or vomiting, your doctor may prescribe medication for you.

Important side effects or signs which you should look out for and what to do if you are affected: Stop taking Dancex SR and contact a doctor or go to your nearest emergency department immediately if you experience any of the following symptoms.
- 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 serious allergic reactions.
- a more slow or shallow breathing (respiratory depression). This is the most serious side effect with an overdose of strong painkillers such as oxycodone and it mostly occurs in elderly and weak patients.

Possible side effects

Very common (may affect more than 1 in 10 people)
- drowsiness, sleepiness, dizziness, headache
- constipation, feeling sick (nausea), vomiting
- itchy skin.

Common (may affect up to 1 in 10 people)
- anxiety, depression, decreased activity, restlessness, increased activity, nervousness, difficulty in sleeping, abnormal thinking, confusion, shaking (tremor)
- lack of energy, feeling weak, tiredness
- shortness of breath, wheezing
- dry mouth, hiccups, indigestion, stomach ache, diarrhoea
- decreased appetite up to loss of appetite
- skin rash, increased sweating
- painful urination, increased urge to urinate.

Uncommon (may affects up to 1 in 100 people)
- a condition where you breathe more slowly and weakly than expected (respiratory depression)
- allergic reactions
- lack of water in the body (dehydration)
- agitation, emotional lability, a feeling of extreme happiness
- hallucinations, derealisation
- vision disturbances, reduction in size of the pupils in the eye
- hearing impaired, a feeling of dizziness or 'spinning' (vertigo)
- change in taste
- increased muscle tension, involuntary muscle contractions, epileptic seizures, convulsions (fits)
- tingling or numbness, reduced sensitivity to pain or touch
- problems with coordination or with keeping one's balance
- loss of memory, concentration impaired, speech disorders
- fainting
- faster heartbeat, feeling your heartbeat (in the context of withdrawal syndrome)
- widening of the blood vessels causing low blood pressure
- coughing, voice changes
- mouth ulcers, sore gums
- wind, difficulty in swallowing, belching
- obstruction of the bowel (ileus)
- decreased sexual desire, impotence, low levels of sex hormones in the blood called hypogonadism (seen in a blood test)
- injuries from accidents
- generally feeling unwell, pain (e.g. chest pain)
- swelling of the hands, ankles or feet (oedema)
- migraine
- drug tolerance
- dry skin
- thirst
- problems passing urine
- chills
- physical dependence including withdrawal symptoms (see section 3 'If you stop taking Dancex SR')
- increase in liver enzymes (seen in a blood test).

Rare (may affect up to 1 in 1,000 people)
- low blood pressure; dizziness, fainting caused by sudden drop in blood pressure when standing up
- bleeding gums, increased appetite, dark-coloured, tarry stools, tooth disorders
- blisters on the skin and the mucous membranes (cold sores or herpes), hives (urticaria)
- changes in body weight (loss or rise).

Frequency not known (frequency cannot be estimated from the available data)
- absence of menstrual bleeding
- serious allergic reaction which causes breathing difficulty or dizziness
- aggression
- increased sensitivity to pain (hyperalgesia)
- dental caries
- biliary colic (which causes stomach pain), biliary congestion
- withdrawal symptoms in newborns
- becoming addicted or reliant on these tablets
- cramping of the smooth muscles
- depression of the cough reflex
- sleep apnoea (breathing pauses during sleep).

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: HPRA Pharmacovigilance; website: www.hpra.ie; By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Dancex SR

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.

5 mg prolonged-release tablets:
PVC/PE/PVDC-aluminium blisters: Do not store above 30°C.
HDPE-Bottles: This medicinal product does not require any special storage conditions.

10 mg, 20 mg prolonged-release tablets:
This medicinal product does not require any special storage conditions.

Shelf life after first opening:
Bottle: 6 months

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 Dancex SR contains
The active substance is oxycodone hydrochloride.
Each prolonged-release tablet contains 5 mg oxycodone hydrochloride equivalent to 4.5 mg oxycodone.
Each prolonged-release tablet contains 10 mg oxycodone hydrochloride equivalent to 9.0 mg oxycodone.
Each prolonged-release tablet contains 20 mg oxycodone hydrochloride equivalent to 17.9 mg oxycodone.
The other ingredients are:
Tablet core: hydrogenated castor oil, copovidone, behenoyl polyoxyglycerides, lactose monohydrate, magnesium stearate, maize starch, colloidal anhydrous silica, triglycerides, medium-chain
Tablet coating: microcrystalline cellulose, hypromellose, stearic acid, titanium dioxide (E171)
5 mg prolonged-release tablet only: indigo carmine (E132) and hydrated aluminium oxide;
20 mg prolonged-release tablet only: iron oxide red (E172).

What Dancex SR looks like and contents of the pack
5 mg prolonged-release tablet:
Blue, round, biconvex film coated prolonged-release tablets.

10 mg prolonged-release tablet:
White, round, biconvex film coated prolonged-release tablets.

20 mg prolonged-release tablet:
Pink, round, biconvex film coated prolonged-release tablets.

The prolonged-release tablets are packed in child resistant PVC/PE/PVDC-aluminium blisters consisting of a white opaque PVC/PE/PVDC laminated foil and an aluminium foil or in a HDPE-Bottle, closed with child resistant Twist-off cap (HDPE or PP) with or without a desiccant capsule of polyethylene (PE), containing silica gel as desiccant.

Pack sizes:
Blister: 7, 10, 14, 20, 28, 30, 50, 56, 60, 98, 100, 100x1 and 112 prolonged-release tablets
Bottle: 100 and 250 prolonged-release tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers
Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany.
Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

This medicinal product is authorised in the Member States of the European Economic Area under the following names:

Germany:	Oxycodon-HCl HEXAL 5 mg Retardtabletten Oxycodon-HCl HEXAL 10 mg Retardtabletten Oxycodon-HCl HEXAL 20 mg Retardtabletten
Ireland:	Dancex SR 5 mg Prolonged-release tablets Dancex SR 10 mg Prolonged-release tablets Dancex SR 20 mg Prolonged-release tablets

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