

PACKAGE LEAFLET: INFORMATION FOR THE USER

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.

In this leaflet:

1. What Dancex SR is and what it is used for
2. What you need to know before you take Dancex SR
3. How to take Dancex SR
4. Possible side effects
5. How to store Dancex SR
6. Contents of the pack and other information

1 What Dancex SR is and what it is used for

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

Dancex SR is used 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 this medicine (listed in section 6)
- if you suffer from severely depressed breathing (respiratory depression)
- 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)
- if you suffer from elevated carbon dioxide levels

Warnings and precautions

Talk to your doctor or pharmacist before taking Dancex SR

- if you are older or debilitated
- if your lung, liver or kidney function is severely impaired
- if you suffer from myxoedema (certain illnesses of the thyroid gland), impaired function of the thyroid gland
- if you suffer from adrenal insufficiency (Addison's disease)
- if you suffer from enlargement of the prostate (prostatic hypertrophy)
- if you suffer from alcoholism or are undergoing alcohol withdrawal
- if you suffer from known opioid-dependence
- if you suffer from inflammation of the pancreas (pancreatitis) or if you have problems with your gall bladder
- if you have difficulty or pain passing urine
- if you have inflammatory bowel disease
- in conditions with increased brain pressure
- if you suffer from disturbances of circulatory regulation
- if you suffer from epilepsy or have a seizure tendency
- if you take MAO inhibitors (for the treatment of depression) or within 2 weeks of discontinuation of their use
- if you are also taking a medicine called naltrexone (see also "Other medicines and Dancex SR")
- if you recently had abdominal surgery.

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 has a primary dependence potential. When used for a long time tolerance to the effects 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. When a patient no longer requires therapy with Dancex SR, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal. 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 and sleeplessness.

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

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.

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.

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

Dancex SR has not been studied in children under 12 years. The safety and efficacy have not been demonstrated and therefore use in children under 12 years of age is not recommended.

Older people

In elderly patients the lowest dose should be administered with careful titration to pain control.

Other medicines and Dancex SR

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

Medicines inducing severe breathing problems such as sleeping pills and strong pain killers can enhance the risk for stopping breathing, especially in the case of overdose and in the elderly.

Taking Dancex SR at the same time as medicines which affect the way the brain works (you may feel very sleepy).

Medicines that affect the way the brain works include:

- other strong pain killers (opioids),
- sleeping pills and tranquillisers,
- certain antidepressants,
- medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics),
- other medicines which act on the nervous system (antipsychotics),
- medicines used to treat Parkinson's disease.

Further interactions may occur with

- certain strong pain killers (so-called mixed agonists-antagonists such as buprenorphine, pentazocine, and nalbuphine).
- medicines against blood clotting (e.g. warfarin). Dancex SR may influence their effects.
- naltrexone, a medicine used in the management of alcohol and opioid dependence.
- certain antibiotics (e.g. clarithromycin, erythromycin, telithromycin and rifampicin)
- certain antifungals (e.g. ketoconazole, voriconazole,

itraconazole, and posaconazole)

- certain medicines to treat HIV infection (e.g. boceprevir, ritonavir, indinavir, nelfinavir and saquinavir)
- cimetidine, a medicine to treat heartburn
- phenytoin, a medicine to treat seizures
- St. John's Wort, a medicine to treat depression

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. It is recommended not to drink grapefruit juice while you're taking Dancex SR.

Pregnancy and breast-feeding

Pregnancy

You should not take Dancex SR during pregnancy. There are no adequate 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 delivery can cause respiratory depression in the newborn.

Breast-feeding

You should not use Dancex SR when you are breast-feeding as oxycodone may pass into breast milk.

Ask your doctor or pharmacist for advice before taking any medicine.

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. To look at the possible side effects affecting the motor skills and concentration see section 4. "Possible side effects". 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.

Important information about some of the ingredients of Dancex SR

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 medicinal product.

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 medicinal product are available.

The recommended dose is

Dancex SR 5 mg

Adults and children (over 12 years of age)

The usual initial dose is two prolonged-release tablets (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 Dancex SR 5 mg according to a fixed schedule need rapidly acting painkillers as rescue medication to control breakthrough pain. Dancex SR 5 mg is not intended for the treatment of breakthrough pain.

For the treatment of non-cancer pain a daily dose of twice daily 20 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.

Dancex SR 10 mg

Adults and children (over 12 years of age)

The usual initial dose is one prolonged-release tablet (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 Dancex SR 10 mg according to a fixed schedule need rapidly acting painkillers as rescue medication to control breakthrough pain. Dancex SR 10 mg is not intended for the treatment of breakthrough pain.

For the treatment of non-cancer pain a daily dose of 4 prolonged-release tablets (twice daily 20 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.

Dancex SR 20 mg

Adults and children (over 12 years of age)

The usual initial dose is 10 mg oxycodone hydrochloride in 12 hourly intervals. 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 Dancex SR 20 mg according to a fixed schedule need rapidly acting painkillers as rescue medication to control breakthrough pain. Dancex SR 20 mg is not intended for the treatment of breakthrough pain.

For the treatment of non-cancer pain a daily dose of two prolonged-release tablets (twice daily 20 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 oxycodone hydrochloride in individual cases.

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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 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 your doctor may prescribe a lower starting dose.

Method and duration 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 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 Dancex SR leads to a rapid release and absorption of a potentially fatal dose of 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 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 Dancex SR than you should

If you have taken more Dancex SR 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 should you expose yourself to situations requiring high levels of concentration e.g. driving a car or using machines.

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.

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 the next dose as directed.

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

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.

When a patient no longer requires 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 product, ask your doctor or pharmacist.

4 Possible side effects

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

Contact a doctor immediately if any of the following symptoms occur:

- **Very slow or weak breathing** (respiratory depression). This is the most serious risk in connection with medicines such as Dancex SR (opioids), and may even be fatal after high doses of this medicine.

OTHER SIDE EFFECTS

Very common (may affect more than 1 in 10 people)

- drowsiness, dizziness, headache.
- constipation, feeling or being sick. Your doctor will prescribe an appropriate medicine to treat these symptoms.
- itching.

Common (may affect up to 1 in 10 people)

- anxiety, depression, nervousness, sleep disorders, abnormal thoughts, confusion, trembling
- feeling weak
- shortness of breath
- dry mouth, general symptoms of indigestion such as stomach ache, diarrhoea, loss of appetite.
- rash, increased sweating, frequent urination.

Uncommon (may affect up to 1 in 100 people)

- allergic reactions
- increase in the amount of a certain hormone (ADH = antidiuretic hormone) in the blood with symptoms such as headache, irritability, lethargy, nausea, vomiting, confusion and disturbance of consciousness.
- lack of water in the body (dehydration).
- restlessness, emotional lability, feeling elated
- hallucinations, drug dependence, vision disturbances, unusual acuteness of hearing, change in taste
- increased or decreased muscle tension, tics, epileptic seizures (fits), reduced sensitivity to pain or touch, problems with coordination or with keeping one’s balance.
- loss of memory, speech disorders
- fainting
- changes in tear secretion, reduction in the size of the pupils.
- increased pulse rate, palpitation of the heart (in the context of withdrawal syndrome).
- widening of the blood vessels causing low blood pressure, increased coughing, sore throat, runny nose, voice changes, difficulty in breathing or wheezing.
- mouth ulcers, sore gums, flatulence (excessive gas in the stomach or bowel), difficulty in swallowing, belching, obstruction of the bowel (ileus).
- decreased sexual desire and impotence.
- injuries due to accidents resulting from decreased alertness, pain (e.g. chest pain), fluid retention (oedema), migraine, withdrawal symptoms, drug tolerance.
- dry skin, thirst
- problems passing urine
- chills

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

- lymph node disease.
- muscle spasms, low blood pressure, sudden drop in blood pressure when standing up
- bleeding gums, increased appetite, dark-coloured stools, tooth staining and other changes of the teeth.
- blisters on the skin and the mucous membranes (cold sores or herpes), increased sensitivity to light, itchy rash.
- blood in urine.
- changes in body weight (loss or rise), skin inflammation.

Very rare (may affect up to 1 in 10,000 people)

- scaly rash.

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)
- caries
- biliary colic (which causes stomach pain), biliary congestion

Prolonged use of Dancex SR may lead to dependence

and a withdrawal syndrome may occur, if treatment is abruptly stopped. If you no longer require treatment with Dancex SR your doctor will gradually decrease the dose to prevent withdrawal symptoms (see also “Warnings and Precautions”).

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 (see below). By reporting side effects you can help provide more information on the safety of this medicine. Reports may be made by following the links to the online reporting option accessible from the IMB homepage, or by completing the downloadable report form also accessible from the IMB website, which may be completed manually and submitted to the IMB via freepost, to the following address:

FREEPOST
Pharmacovigilance Section
Irish Medicines Board
Kevin O’Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

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.

HDPE-Twist-off containers

Shelf life after first opening: 6 months

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 Dancex SR contains

The active substance is oxycodone hydrochloride.

Each prolonged-release tablet contains 5 mg/10 mg/20 mg oxycodone hydrochloride equivalent to 4.5 mg/9.0 mg/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 (E 171) Dancex SR 5 mg: indigo carmine aluminium salt; Dancex SR 20 mg: iron oxide red (E 172).

What Dancex SR looks like and contents of the pack

Dancex SR 5 mg are blue, round, biconvex prolonged-release tablets.

Dancex SR 10 mg are white, round, biconvex prolonged-release tablets.

Dancex SR 20 mg are pink, round, biconvex prolonged-release tablets.

Dancex SR is available in packs of 7, 10, 14, 20, 28, 30, 50, 56, 60, 98, 100, 100x1 and 112 prolonged-release tablets in blisters and 100 and 250 prolonged-release tablets in HDPE bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany.
Salutas Pharma GmbH, Dieselstraße 5, 70839 Gerlingen, Germany.
Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

This medicinal product is authorised in the Member States of the EEA 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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