Package leaflet: Information for the patient

Dancex SR Plus 5 mg/2.5 mg Prolonged-release tablets
Dancex SR Plus 10 mg/5 mg Prolonged-release tablets
Dancex SR Plus 20 mg/10 mg Prolonged-release tablets
Dancex SR Plus 40 mg/20 mg Prolonged-release tablets

oxycodone hydrochloride/naloxone 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

1. What Dancex SR Plus is and what it is used for

Dancex SR Plus is a prolonged-release tablet, which means that its active substances are released over an extended period. Their action lasts for 12 hours.

These tablets are only for use in adults.

Pain relief
You have been prescribed Dancex SR Plus for the treatment of severe pain, which can be adequately managed only with opioid analgesics. Naloxone hydrochloride is added to counteract constipation.

How these tablets work in pain relief
Dancex SR Plus contains oxycodone hydrochloride and naloxone hydrochloride as active substances. Oxycodone hydrochloride is responsible for the pain-killing effect of Dancex SR Plus, and is a potent analgesic (“painkiller”) of the opioid group.

The second active substance of Dancex SR Plus, naloxone hydrochloride, is intended to counteract constipation. Bowel dysfunction (e.g. constipation) is a typical side effect of treatment with opioid painkillers.

2. What you need to know before you take Dancex SR Plus

Do not take Dancex SR Plus
- if you are allergic to oxycodone hydrochloride, naloxone hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- if you have breathing problems, such as breathing more slowly or weakly than expected (respiratory depression)
- if you suffer from a severe chronic lung disease associated with narrowing of the airways (chronic obstructive pulmonary disease or COPD)

- if you suffer from a condition known as Cor pulmonale. In this condition the right side of the heart becomes enlarged, due to increased pressure inside blood vessels in the lung etc. (e.g. as a result of COPD – see above)
- if you suffer from severe bronchial asthma
- if you have paralytic ileus (a type of bowel obstruction) not caused by opioids
- if you have moderate to severe liver problems.

Warnings and precautions
Talk to your doctor or pharmacist before taking Dancex SR Plus
- if you are elderly or debilitated (weak)
- if you have paralytic ileus (a type of bowel obstruction) caused by opioids
- if you have kidney problems
- if you have mild liver problems
- if you have severe lung problems (i.e. reduced breathing capacity)
- if you suffer from frequent breathing stops during the night which may make you feel very sleepy during the day (sleep apnoea)
- if you have myxoedema (a thyroid disorder, with dryness, coldness and swelling [‘puffiness’] of the skin, affecting the face and limbs)
- if your thyroid gland is not producing enough hormones (underactive thyroid, or hypothyroidism)
- if your adrenal glands are not producing enough hormones (adrenal insufficiency, or Addison’s disease)
- if you have a mental illness accompanied by a (partial) loss of reality (psychosis), due to alcohol or intoxication with other substances (substance-induced psychosis)
- if you suffer from gallstone problems
- if your prostate gland is abnormally enlarged (prostate hypertrophy)
- if you suffer from alcoholism or delirium tremens
- if your pancreas is inflamed (pancreatitis)
- if you have low blood pressure (hypotension)
- if you have high blood pressure (hypertension)
- if you have pre-existing cardiovascular disease
- if you have a head injury (due to the risk of increased brain pressure)
- if you suffer from epilepsy or are prone to fits
- if you are also taking MAO inhibitors (used to treat depression, Parkinson’s disease or bacterial infections), e.g. medicines containing tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid
- if you feel sleepy or if you suddenly fall asleep sometimes.

This medicine can cause breathing problems while sleeping. These problems may include pauses in breathing during sleep, being awoken by shortness of breath, difficulty staying asleep or excessive daytime drowsiness. If you or someone else observes these symptoms contact your doctor. Your doctor may want to lower your dose.

Tell your doctor if any of the above has ever applied to you in the past. Also, please tell your doctor if you develop any of the above disorders while you are taking Dancex SR Plus.

The most serious result of opioid overdose is **respiratory depression** (slow and shallow breathing). This may also cause blood oxygen levels to fall, resulting in possible fainting, etc.

Tell your doctor in case you have cancer associated to peritoneal metastases or beginning bowel obstruction in advanced stages of digestive and pelvic cancers.

If you experience severe diarrhoea at the start of treatment, this may be due to the effect of naloxone. It may be a sign that bowel function is returning to normal. Such diarrhoea can occur within the first 3-5

days of treatment. If diarrhoea should persist after 3-5 days, or give you cause for concern, please contact your doctor.

If you have been using another opioid, withdrawal symptoms may occur when you initially switch to Dancex SR Plus treatment, e.g. restlessness, bouts of sweating and muscle pain. If you experience such symptoms, you may need to be specially monitored by your doctor.

Similar to other opioids, oxycodone may affect the normal production of hormones in the body such as cortisol or sex hormones, particularly if you have taken high doses for long periods of time. If you experience symptoms which persist, such as feeling or being sick (including vomiting), loss of appetite, tiredness, weakness, dizziness, changes in menstrual cycle, impotence, infertility or decreased sex drive, talk to your doctor as he/she may want to monitor your hormone levels.

Surgery
If you need to undergo surgery, please tell your doctors that you are taking Dancex SR Plus.

Long-term treatment
If used over the long term, you may become tolerant to Dancex SR Plus. This means you may need a higher dose to achieve the desired pain relief. Also, long-term use of Dancex SR Plus may lead to physical dependence. Withdrawal symptoms may occur if treatment is stopped too suddenly (restlessness, bouts of sweating, muscle pain). If you no longer need treatment, you should reduce your daily dose gradually, in consultation with your doctor.

Psychological dependence
The active substance oxycodone hydrochloride alone has an abuse profile similar to other strong opioids (strong analgesics). There is potential for development of psychological dependence. Oxycodone hydrochloride containing products should be avoided in patients with a present or past abuse of alcohol, drugs or medicines.

Incorrect use of Dancex SR Plus
These tablets are not suitable for withdrawal treatment.

5 mg/2.5 mg:
The tablet must be swallowed whole and not be divided, broken, chewed or crushed.
Taking divided, broken, chewed or crushed tablets may lead to the absorption of a potentially lethal dose of oxycodone hydrochloride (see under section 3. “If you take more Dancex SR Plus than you should”).

10 mg/5 mg; 20 mg/10 mg; 40 mg/20 mg:
The tablet must not be broken, chewed or crushed. However, the tablets can be divided into equal halves (see section 3. “Method of administration”). Taking broken, chewed or crushed tablets may lead to the absorption of a potentially lethal dose of oxycodone hydrochloride (see under section 3. “If you take more Dancex SR Plus than you should”).

Dancex SR Plus should never be abused, particularly if you have a drug addiction. If you are addicted to substances such as heroin, morphine or methadone, severe withdrawal symptoms are likely if you abuse Dancex SR Plus because it contains the active substance naloxone. Pre-existing withdrawal symptoms may be made worse.

You should never misuse these tablets by dissolving and injecting them (e.g. into a blood vessel). In particular, they contain talc, which can cause destruction of local tissue (necrosis) and changes in lung tissue (lung granuloma). Such abuse can also have other serious consequences and may even be fatal.

You may see residue of the tablet in your stool. Do not worry, as the active substances (oxycodone hydrochloride and naloxone hydrochloride) have been released earlier while the tablet passed through the stomach and gut and have started to be effective in your body.

Doping
Athletes must be aware that this medicine may cause a positive reaction to 'anti-doping' tests. The use of **Dancex SR Plus** as a doping agent may become a health hazard.

Children and adolescents
Dancex SR Plus has not yet been studied in children and adolescents under 18 years of age. Its safety and effectiveness have not been proven in children and adolescents. For this reason, Dancex SR Plus use in children and adolescents under 18 years of age is not recommended.

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

Concomitant use of Dancex SR Plus and sedative medicines such as benzodiazepines or related medicines (medicines which affect the brain function 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 Plus 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.

These medicines which affect the brain function are for example:
- other strong painkillers (opioids)
- medicines to treat epilepsy, pain, and anxiety such as gabapentin and pregabalin
- sleep medication and tranquillisers (sedative medicines including benzodiazepines, hypnotics, anxiolytics)
- medicines to treat depression
- medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics)
- medicines to treat psychiatric or mental disorders (phenothiazines, neuroleptics, antipsychotics).

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.

If you take Dancex SR Plus at the same time as you take other medicines, the effects of Dancex SR Plus or the other medicines may be changed. Tell your doctor if you are taking:
- medicines that decrease the blood's clotting ability (coumarin derivatives), this clotting time may be speeded up or slowed down
- antibiotics of the macrolide type (such as clarithromycin, erythromycin or telithromycin)
- antifungal medicines of the azole type (such as ketoconazole, voriconazole, itraconazole or posaconazole)
- certain medicines used to treat HIV infections (protease inhibitors, such as ritonavir indinavir, nelfinavir or saquinavir)
- cimetidine (used to treat stomach ulcers, indigestion or heartburn)
- rifampicin (used to treat tuberculosis)
- carbamazepine (used to treat seizures, fits or convulsions and certain pain conditions)
- phenytoin (used to treat seizures, fits or convulsions)
- St John's wort (a herbal remedy to treat depression also known as *Hypericum perforatum*)
- quinidine (a medicine to treat an irregular heartbeat).

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

You should avoid drinking grapefruit juice while you are taking Dancex SR Plus.

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**
  Use of Dancex SR Plus should be avoided to the extent possible during pregnancy. If used over prolonged periods during pregnancy, oxycodone hydrochloride may lead to withdrawal symptoms in the newborn baby. If oxycodone hydrochloride is given during childbirth, the baby may have breathing problems (respiratory depression).

- **Breast-feeding**
  Breast-feeding should be stopped during treatment with Dancex SR Plus. Oxycodone hydrochloride passes into breast milk. It is not known whether naloxone hydrochloride also passes into breast milk. Therefore, a risk for the suckling infant cannot be excluded in particular following intake of multiple doses of Dancex SR Plus.

Driving and using machines
Dancex SR Plus can affect your ability to drive or operate machines. This is most likely at the start of Dancex SR Plus therapy, after a dose increase or after switching from a different medication. However, these side effects should disappear once you are on a stable Dancex SR Plus dose.

Dancex SR Plus has been associated with sleepiness and episodes of suddenly falling asleep. If you have this side effect, you must not drive or operate machinery. Talk to your doctor if these side effects occur.

Ask your doctor whether you may drive or operate machines.

Dancex SR Plus contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per prolonged-release tablets, that is to say essentially 'sodium-free'.

3. How to take Dancex SR Plus

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

Dancex SR Plus is a prolonged-release tablet, which means that its active substances are released over an extended period. Their action lasts for 12 hours.

Unless otherwise prescribed by your doctor, the usual dose is:
To treat pain
Adults
The usual starting dose is 10 mg oxycodone hydrochloride/5 mg naloxone hydrochloride as prolonged-release tablet(s) every 12 hours.

Your doctor will decide how much Dancex SR Plus you should take every day and how to divide your total daily dose into morning and evening doses. Your doctor will also decide on any necessary dose adjustments during treatment. Your dose will be adjusted according to your level of pain and individual

sensitivity. You should be given the lowest dose needed for pain relief. If you have already been treated with opioids, Dancex SR Plus treatment can be started at a higher dose.

The maximum daily dose is 160 mg oxycodone hydrochloride and 80 mg naloxone hydrochloride. If you need a higher dose, your doctor may give you additional oxycodone hydrochloride without naloxone hydrochloride. However, the maximum daily dose of oxycodone hydrochloride should not exceed 400 mg. The beneficial effect of naloxone hydrochloride on bowel activity may be affected if additional oxycodone hydrochloride is given without additional naloxone hydrochloride.

If you are switched from Dancex SR Plus to another strong opioid pain medication you have to anticipate, that your bowel function will probably worsen.

If you experience pain between two doses of Dancex SR Plus, you probably may need a rapid-acting painkiller. Dancex SR Plus is not suitable for this. In this case, please talk to your doctor.

If you have the impression that the effect of Dancex SR Plus is too strong or too weak, please talk to your doctor or pharmacist.

Elderly patients
In general, no dose adjustment is necessary for older patients with normal kidney and/or liver function.

Liver or kidney problems
If you have an impairment of your kidney function or a mild impairment of your liver function, your attending doctor will prescribe Dancex SR Plus with special caution. If you have a moderate or severe impairment of liver function, Dancex SR Plus must not be used (see also section 2 “Do not take Dancex SR Plus” and “Warnings and precautions”).

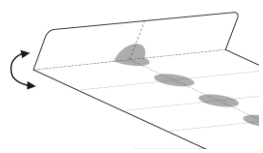
Method of administration
Oral use.
- You should take Dancex SR Plus with a glass of water.
- *Dancex SR Plus 5 mg/2.5 mg:*
  The tablet must be swallowed whole and not divided, broken, chewed or crushed.
  Dancex SR Plus 10 mg/5 mg;20 mg/10 mg; 40 mg/20 mg:
  The tablet can be divided into equal doses. The tablet must not be broken, chewed or crushed.
- You can take the prolonged-release tablets with or without food.

Take Dancex SR Plus every 12 hours, according to a fixed time schedule (e.g. at 8 o’clock in the morning and 8 o’clock in the evening).

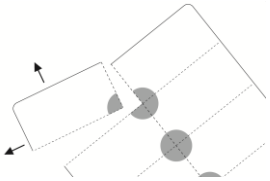
Peel-off blisters:
How to remove the tablets from the child-resistant blister
The tablets are packaged in a child-resistant perforated unit dose blister.
Do not push the tablets **through** the blister foil.

Remove the tablets as follows:

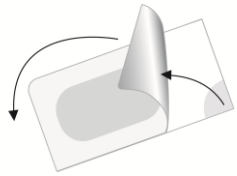
1. Buckle the blister along the perforation line back and forth.



2. Separate one cell from the blister at the perforation lines.



3. Peel off the foil slowly starting at the marked corner to open the pocket.



Remove the tablet.

Push through blister packs:
How to remove the tablets from the child-resistant blister
The tablets are packed in a child-resistant perforated unit dose blister.
To remove a tablet, press the tablet through the reinforced blister foil.

Duration of use
In general, you should not take Dancex SR Plus for any longer than you need to. If you are on long-term treatment with Dancex SR Plus your doctor should regularly check whether you still need Dancex SR Plus.

If you take more Dancex SR Plus than you should
If you have taken more than the prescribed dose of Dancex SR Plus you must **inform your doctor immediately**.
An overdose may result in:
- narrowed pupils
- slow and shallow breathing (respiratory depression)
- drowsiness up to loss of consciousness)
- low muscle tone (hypotonia)
- reduced pulse rate, and
- a drop in blood pressure.

In severe cases, loss of consciousness (coma), fluid on the lungs and circulatory collapse may occur, which may be fatal in some cases.

You should avoid situations which require a high level of alertness, e.g. driving.

If you forget to take Dancex SR Plus
If you forget to take Dancex SR Plus or if you take a dose lower than the one prescribed, you may not feel any painkilling effect.
If you should forget to take your dose, please follow the instructions below:
- If your next usual dose is due in 8 hours or more: take the forgotten dose immediately and continue with your normal dosing schedule.
- If your next usual dose is due within less than 8 hours: take the forgotten dose. Then, wait another 8 hours before taking your next dose. Try to get back on track with your original dosing schedule (e.g. 8 o'clock in the morning and 8 o'clock in the evening). 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 Plus
Do not stop your treatment with Dancex SR Plus without consulting your doctor.

If you do not require any further treatment, you must reduce the daily dose gradually after talking to your doctor. In this way, you will avoid withdrawal symptoms, such as restlessness, bouts of sweating and muscle pain.

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.

Important side effects to look out for, and what to do if you are affected
If you are affected by any of the following important side effects, consult your nearest doctor immediately.

Slow and shallow breathing (respiratory depression) is the main danger of an opioid overdose. It mostly occurs in elderly and debilitated (weak) patients. Opioids can also cause a severe drop in blood pressure in susceptible patients.

The following side effects were observed in patients being treated for pain:

Common (may affect up to 1 in 10 people)
- decreased appetite up to loss of appetite
- difficulty in sleeping, tiredness or debility
- a feeling of dizziness or 'spinning', headache, drowsiness
- hot flushes
- abdominal pain, constipation, diarrhoea, dry mouth, indigestion, being sick, feeling sick, wind
- itchy skin, skin reactions, increased sweating
- feeling of unusual weakness.

Uncommon (may affect up to 1 in 100 people)
- hypersensitivity/ allergic reactions
- restlessness, abnormal thoughts, anxiety, confusion, depression, nervousness
- reduced sexual drive
- epileptic seizures (especially in persons with epileptic disorder or predisposition to seizures), difficulties to concentrate, altered taste, speech disorder, fainting, shaking, lack of energy
- vision impairment
- chest tightness especially if you already have coronary heart disease, palpitations
- drop in blood pressure, rise in blood pressure
- difficulties of breathing, runny nose, cough
- abdominal bloating
- hepatic enzymes increased, biliary colic
- muscle cramps, muscle twitches, muscle pain
- increased urge to urinate
- withdrawal symptoms such as agitation
- chest pain
- chills, generally feeling unwell, pain, thirst
- swelling of hands, ankles or feet
- weight loss
- injuries from accidents.

Rare (may affect up to 1 in 1,000 people)
- increase in pulse rate
- drug dependence
- yawning

- dental changes
- weight gain.

Frequency not known (frequency cannot be estimated from the available data)
- euphoric mood, hallucinations, nightmares, aggression
- pins and needles, severe drowsiness
- shallow breathing
- belching
- difficulties in passing urine
- erectile dysfunction
- problems with breathing during sleep (sleep apnoea syndrome).

The active substance oxycodone hydrochloride, if not combined with naloxone hydrochloride, is known to have the following differing side effects:
Oxycodone can cause breathing problems (respiratory depression), reduction in size of the pupil in the eye, cramping of the bronchial muscles and cramping of the smooth muscles, as well as depression of the cough reflex.

Common (may affect up to 1 in 10 people)
- altered mood and personality changes (e.g. depression, feeling of extreme happiness), decreased activity, increased activity
- hiccups
- difficulty in passing urine.

Uncommon (may affect up to 1 in 100 people)
- dehydration
- agitation, perception disturbances (e.g. hallucination, derealisation)
- impaired concentration, migraines, increased muscle tension, involuntary muscle contractions, reduced sensitivity to pain or touch, abnormal coordination
- difficulties in hearing
- widening of the blood vessels
- vocal changes (dysphonia)
- difficulties in swallowing
- a condition where the bowel stops working properly (ileus)
- mouth ulcers, sore gums
- dry skin
- a decrease in the concentration of sex hormones, which may affect sperm production in men or the menstrual cycle in women
- swelling due to water retention, drug tolerance.

Rare (may affect up to 1 in 1,000 people)
- infections such as cold sores or herpes (which may cause blisters around the mouth or genital area)
- increased appetite
- black (tarry) stools, bleeding gums
- itching rash (urticaria).

Frequency not known (frequency cannot be estimated from the available data)
- acute generalised allergic reactions (anaphylactic reactions)
- increased pain sensitivity
- tooth decay
- problems with bile flow
- absence of menstrual periods
- withdrawal symptoms in the newborn.

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 Plus

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 carton, bottle or blister after "EXP". The expiry date refers to the last day of that month.

Blister:
Do not store above 25°C.

Bottles:
Do not store above 30°C.
Shelf life after first opening:
3 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 Plus contains
The active substances are oxycodone hydrochloride and naloxone hydrochloride.

Dancex XR Plus 5 mg/2.5 mg:
Each prolonged-release tablet contains 5 mg of oxycodone hydrochloride (equivalent to 4.5 mg oxycodone) and 2.5 mg of naloxone hydrochloride (as 2.74 mg naloxone hydrochloride dihydrate, equivalent to 2.25 mg naloxone).

The other ingredients are:
Tablet core
Polyvinyl acetate
Povidone K30
Sodium laurilsulfate
Silica, colloidal anhydrous
Cellulose, microcrystalline
Magnesium stearate

Tablet coating
Polyvinyl alcohol
Titanium dioxide (E171)
Macrogol 3350
Talc

Dancex SR Plus 10 mg/5 mg:
Each prolonged-release tablet contains 10 mg of oxycodone hydrochloride (equivalent to 9 mg oxycodone) and 5 mg of naloxone hydrochloride (as 5.45 mg naloxone hydrochloride dihydrate, equivalent to 4.5 mg naloxone).

The other ingredients are:
Tablet core

Polyvinyl acetate
Povidone K30
Sodium laurilsulfate
Silica, colloidal anhydrous
Cellulose, microcrystalline
Magnesium stearate

Tablet coating
Polyvinyl alcohol
Titanium dioxide (E171)
Macrogol 3350
Talc
Iron oxide red (E172)

Dancex SR Plus 20 mg/10 mg:
Each prolonged-release tablet contains 20 mg of oxycodone hydrochloride (equivalent to 18 mg oxycodone) and 10 mg of naloxone hydrochloride (as 10.9 mg naloxone hydrochloride dihydrate, equivalent to 9 mg naloxone).

The other ingredients are:
Tablet core
Polyvinyl acetate
Povidone K30
Sodium laurilsulfate
Silica, colloidal anhydrous
Cellulose, microcrystalline
Magnesium stearate

Tablet coating
Polyvinyl alcohol
Titanium dioxide (E171)
Macrogol 3350
Talc

Dancex SR Plus 40 mg/20 mg:
Each prolonged-release tablet contains 40 mg of oxycodone hydrochloride (equivalent to 36 mg oxycodone) and 20 mg of naloxone hydrochloride (as 21.8 mg naloxone hydrochloride dihydrate, equivalent to 18 mg naloxone).

The other ingredients are:
Tablet core
Polyvinyl acetate
Povidone K30
Sodium laurilsulfate
Silica, colloidal anhydrous
Cellulose, microcrystalline
Magnesium stearate

Tablet coating
Polyvinyl alcohol
Titanium dioxide (E171)
Macrogol 3350
Talc
Iron oxide red (E172)

What Dancex SR Plus looks like and contents of the pack
Dancex SR Plus 5 mg/2.5 mg:
White, round, biconvex prolonged-release tablet with a diameter of 4.7 mm and a height of 2.9 - 3.9 mm.

Dancex SR Plus 10 mg/5 mg:
Pink, oblong, biconvex prolonged-release tablet with break scores on both sides, with a length of 10.2 mm, a width of 4.7 mm and a height of 3.0 - 4.0 mm. The tablet can be divided into equal doses.

Dancex SR Plus 20 mg/10 mg:
White, oblong, biconvex prolonged-release tablet with break scores on both sides, with a length of 11.2 mm, a width of 5.2 mm and a height of 3.3 - 4.3 mm. The tablet can be divided into equal doses.

Dancex SR Plus 40 mg/20 mg:
Pink, oblong, biconvex prolonged-release tablet with break scores on both sides, with a length of 14.2 mm, a width of 6.7 mm and a height of 3.6 - 4.6 mm. The tablet can be divided into equal doses.

Dancex SR Plus is available in child resistant, perforated, aluminium/PVC/PE/PVDC, unit dose peel-off or push through blister of 10x1 (hospital pack), 14x1, 20x1, 28x1, 30x1, 50x1, 56x1, 60x1, 98x1 and 100x1 prolonged-released tablets or child resistant, aluminium/PVC/PE/PVDC blister of 28, 56 and 84 prolonged-released tablets or HDPE bottles with child-resistant screw cap containing 50 and 100 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
Develco Pharma GmbH., Grienmatt 27, Baden-Wuerttemberg 79650 Schopfheim, Germany.
Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland)under the following names:

Czech Republic:	Oxycodon/Naloxon Sandoz
Finland:	Tanonalla 5 mg/2,5 mg depottabletti
	Tanonalla 10 mg/5 mg depottabletti
	Tanonalla 20 mg/10 mg depottabletti
	Tanonalla 30 mg/15 mg depottabletti
	Tanonalla 40 mg/20 mg depottabletti
Germany:	Oxycodon comp - HEXAL 5 mg/2,5 mg Retardtabletten
	Oxycodon comp - HEXAL 10 mg/5 mg Retardtabletten
	Oxycodon comp - HEXAL 20 mg/10 mg Retardtabletten
	Oxycodon comp - HEXAL 30 mg/15 mg Retardtabletten
	Oxycodon comp - HEXAL 40 mg/20 mg Retardtabletten
Iceland:	Tanonalla 5 mg/2,5 mg forðatafla
	Tanonalla 10 mg/5 mg forðatafla
	Tanonalla 20 mg/10 mg forðatafla
	Tanonalla 40 mg/20 mg forðatafla
Ireland:	Dancex SR Plus 5 mg/2.5 mg Prolonged-release tablets
	Dancex SR Plus 10 mg/5 mg Prolonged-release tablets
	Dancex SR Plus 20 mg/10 mg Prolonged-release tablets
	Dancex SR Plus 40 mg/20 mg Prolonged-release tablets
Italy:	Dolstip
Norway:	Tanonalla 5 mg/2,5 mg depottablett

	Tanonalla 10 mg/5 mg depottablett
	Tanonalla 20 mg/10 mg depottablett
	Tanonalla 30 mg/15 mg depottablett
	Tanonalla 40 mg/20 mg depottablett
Poland:	Xanconalon
Portugal :	Oxicodona + Naloxona Sandoz 5mg/2,5 mg comprimidos revestidos por película
	Oxicodona + Naloxona Sandoz 10mg/5 mg comprimidos revestidos por película
	Oxicodona + Naloxona Sandoz 20mg/10 mg comprimidos revestidos por película
	Oxicodona + Naloxona Sandoz 30mg/15 mg comprimidos revestidos por película
	Oxicodona + Naloxona Sandoz 40mg/20 mg comprimidos revestidos por película
Spain:	Tanonalla 5 mg/2,5 mg comprimidos de liberación prolongada EFG
	Tanonalla 10 mg/5 mg comprimidos de liberación prolongada EFG
	Tanonalla 20 mg/10 mg comprimidos de liberación prolongada EFG
	Tanonalla 40 mg/20 mg comprimidos de liberación prolongada EFG
Slovenia:	Codilek Combo 5 mg/2,5 mg tablete s podaljšanim sproščanjem
	Codilek Combo 10 mg/5 mg tablete s podaljšanim sproščanjem
	Codilek Combo 20 mg/10 mg tablete s podaljšanim sproščanjem
	Codilek Combo 30 mg/15 mg tablete s podaljšanim sproščanjem
	Codilek Combo 40 mg/20 mg tablete s podaljšanim sproščanjem
Slovakia:	Oxycodone/Naloxone Sandoz 5 mg/2,5 mg
	Oxycodone/Naloxone Sandoz 10 mg/5 mg
	Oxycodone/Naloxone Sandoz 20 mg/10 mg
	Oxycodone/Naloxone Sandoz 40 mg/20 mg
Sweden:	Oxycodone/Naloxone Sandoz 5 mg/2,5 mg depottabletter
	Oxycodone/Naloxone Sandoz 10 mg/5 mg depottabletter
	Oxycodone/Naloxone Sandoz 20 mg/10 mg depottabletter
	Oxycodone/Naloxone Sandoz 30 mg/15 mg depottabletter
	Oxycodone/Naloxone Sandoz 40 mg/20 mg depottabletter
United Kingdom:	Doneloxon 5 mg/2.5 mg Prolonged-release tablets
	Doneloxon 10 mg/5 mg Prolonged-release tablets
	Doneloxon 20 mg/10 mg Prolonged-release tablets
	Doneloxon 40 mg/20 mg Prolonged-release tablets

This leaflet was last revised in 06/2022.