Package leaflet: Information for the user

[Product Name] 5 mg/2.5 mg prolonged-release tablets
[Product Name] 10 mg/5 mg prolonged-release tablets
[Product Name] 20 mg/10 mg prolonged-release tablets
[Product Name] 30 mg/15 mg prolonged-release tablets
[Product Name] 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 [Product Name] is and what it is used for

[Product Name] 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 [Product Name] for the treatment of severe pain, which can be adequately managed only with opioid analgesics. Naloxone hydrochloride is added to counteract constipation.

How [Product Name] works in pain relief
[Product Name] contains oxycodone hydrochloride and naloxone hydrochloride as active substances. Oxycodone hydrochloride is responsible for the pain-killing effect of [Product Name], and is a potent analgesic ("painkiller") that belongs to a group of medicines called opioids.

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

Restless legs syndrome
You have been prescribed [Product Name] for the second line symptomatic treatment of severe to very severe restless legs syndrome in people who cannot be treated with dopamine medicines. People with restless legs syndrome have unpleasant sensations in their limbs. This can start as soon as they sit or lie down and is only relieved by an irresistible urge to move the legs, sometimes the arms and other parts of the body. It makes sitting still and sleeping very difficult. Naloxone hydrochloride is added to counteract constipation.

How [Product Name] works in restless legs syndrome

These tablets help to relieve the unpleasant sensations and so reduce the urge to move the limbs. The second active substance of [Product Name], naloxone hydrochloride, is intended to counteract constipation. Bowel dysfunction (e.g. constipation) is a typical side effect of treatment with opioids.

2. What you need to know before you take [Product Name]

Do not take [Product Name]
- if you are allergic to oxycodone hydrochloride, naloxone hydrochloride or any of the other ingredients of this medicine (listed in section 6),
- if your breathing is not able to supply enough oxygen to the blood, and get rid of carbon dioxide produced in the body (respiratory depression),
- if you suffer from a severe 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 dysfunction.

Additionally for restless legs syndrome
- if you have a history of opioid abuse

Warnings and precautions
Talk to your doctor or pharmacist before taking [Product Name]
- if you are elderly or debilitated (weak),
- if you have paralytic ileus (a type of bowel obstruction) caused by opioids,
- if you have kidney impairment,
- if you have mild liver impairment,
- if you have severe lung impairment (i.e. reduced breathing capacity),
- if you suffer from a condition characterised by frequent breathing stops during the night which may make you feel very sleepy during the daytime (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 seizures,
- if you are also taking MAO inhibitors (used to treat depression or Parkinson’s disease), or you have taken this type of medicine in the last two weeks, e.g. medicines containing tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid,
- if sleepiness or episodes of suddenly falling asleep occur.

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 [Product Name]. 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.

Diarrhoea
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 gives you cause for concern, please contact your doctor.

Switching to [Product Name]
If you have been using another opioid, withdrawal symptoms may occur when you initially switch to [Product Name] 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.

Long-term treatment
If taken over the long term, you may become tolerant to [Product Name]. This means you may need a higher dose to achieve the desired effect. Also, long-term use of [Product Name] 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.

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

Surgery
If you need to undergo surgery, please tell your doctor that you are taking [Product Name].

Effect on the production of hormones
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.

Hyperalgesia
This medicine may increase your sensitivity to pain particularly at high doses. Tell your doctor if this happens. A reduction in your dose or a change in your medicine may be necessary.

Remnants in stool
You may notice remnants of the prolonged release tablet in your stools. Do not be alarmed, as the active substances (oxycodone hydrochloride and naloxone hydrochloride) have already been released in the stomach and gut and absorbed into your body.

Incorrect use of [Product Name]
[Product Name] is not suitable for withdrawal treatment.

[Product Name] 5 mg/2.5 mg
The prolonged-release tablet must be swallowed whole and must 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 section 3 'If you take more [Product Name] than you should').

[Product Name] 10 mg/5 mg, 20 mg/10 mg, 30 mg/15 mg, 40 mg/20 mg
The prolonged-release tablet can be divided into equal doses but must not be chewed or crushed. Taking chewed or crushed tablets may lead to the absorption of a potentially lethal dose of oxycodone hydrochloride (see section 3 'If you take more [Product Name] than you should').

Abuse
[Product Name] 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 [Product Name] because it contains the ingredient naloxone. Pre-existing withdrawal symptoms may be made worse.

Misuse
You should never misuse [Product Name] prolonged-release 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.

Doping
Athletes must be aware that this medicine may cause a positive reaction to 'anti-doping' tests. The use of [Product Name] as a doping agent may become a health hazard.

Other medicines and [Product Name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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.

Concomitant use of opioids, including oxycodone hydrochloride 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 [Product Name] 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. Examples of these sedatives or related medicines include:
- other potent painkillers (opioids);
- medicines to treat epilepsy, pain, and anxiety such as gabapentin and pregabalin;
- sleep medication and tranquilisers (sedatives 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 (antipsychotics which includes phenothiazines and neuroleptics).

If you take these tablets at the same time as you take other medicines, the effect of these tablets or the other medicine as described below 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);
- a specific type of medicine known as a protease inhibitor used to treat HIV (examples include ritonavir, indinavir, nelfinavir or saquinavir);
- cimetidine (a medicine for 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);
- a herbal remedy called St John's Wort (also known as Hypericum perforatum);
- quinidine (a medicine to treat an irregular heartbeat).

No interactions are expected between [Product Name] and paracetamol, acetylsalicylic acid or naltrexone.

[Product Name] with food, drink and alcohol
Drinking alcohol whilst taking [Product Name] may make you feel more sleepy or increase the risk of serious side effects such as shallow breathing with a risk of stopping breathing, and loss of consciousness. It is recommended not to drink alcohol while you are taking [Product Name].

You should avoid drinking grapefruit juice while you are taking [Product Name].

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
Use of [Product Name] during pregnancy should be avoided unless your doctor thinks treatment with this medicine is essential. If used over prolonged periods during pregnancy, oxycodone hydrochloride may lead to withdrawal symptoms in newborn infants. If oxycodone hydrochloride is given during childbirth, respiratory depression (slow and shallow breathing) may occur in the newborn infant.

Breast-feeding
Breast-feeding should be discontinued during treatment with [Product Name]. 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 [Product Name].

Driving and using machines
[Product Name] may affect your ability to drive or operate machines as it may make you sleepy or dizzy. In particular, this is likely at the start of [Product Name] therapy, after a dose increase or after switching from a different medication. However, these side effects should disappear once you are on a stable dose.

This medicine has been associated with sleepiness and episodes of suddenly falling asleep. If you experience these side effects, you must not drive or operate machinery. You should tell your doctor if this occurs.

Ask your doctor whether you may drive or operate machines.

[Product Name] contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take [Product Name]

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

[Product Name] is a prolonged-release tablet, which means that its active substances are released over an extended period. Their action lasts for 12 hours.

[Product Name] 5 mg/2.5 mg
The prolonged-release tablet must be swallowed whole and must 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 section 3 'If you take more [Product Name] than you should').

[Product Name] 10 mg/5 mg, 20 mg/10 mg, 30 mg/15 mg, 40 mg/20 mg
The prolonged-release tablet can be divided into equal doses but must not be chewed or crushed. Taking chewed or crushed tablets may lead to the absorption of a potentially lethal dose of oxycodone hydrochloride (see section 3 'If you take more [Product Name] than you should').

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 [Product Name] 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, [Product Name] 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 [Product Name] to another strong opioid pain medication your bowel function will probably worsen.

If you experience pain between two doses of [Product Name], you may need to take an additional rapid-acting painkiller. [Product Name] is not suitable for this. In this case, please talk to your doctor.

If you have the impression that the effect of [Product Name] is too strong or too weak, please talk to your doctor or pharmacist.

To treat restless legs syndrome

Adults
The usual starting dose is 5 mg oxycodone hydrochloride/ 2.5 mg naloxone hydrochloride as prolonged-release tablet(s) every 12 hours.

Your doctor will decide how much [Product Name] you should take every day and how to divide your total daily dosage into morning and evening doses. They will also decide on any necessary dose adjustments during treatment. Your dose will be adjusted according to your individual sensitivity. You should be given the lowest dose needed to relieve your restless legs syndrome symptoms.

If you feel that these tablets are too strong or too weak, please talk to your doctor or pharmacist.

The maximum daily dose is 60 mg oxycodone hydrochloride and 30 mg naloxone hydrochloride.

For doses not realisable/practicable with this strength other strengths of this medicinal product are available.

To treat pain or restless legs syndrome

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

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

Use in children and adolescents below 18 years of age
[Product Name] 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, [Product Name] use in children and adolescents under 18 years of age is not recommended.

Method of administration
[Product Name] 5 mg/2.5 mg tablets
These tablets are for oral use. You should take [Product Name] with sufficient liquid (½ glass of water). The tablet must be swallowed whole and not divided, broken, chewed or crushed. The tablet may be taken with or without food.

[Product Name] 10 mg/5 mg, 20 mg/10 mg, 30 mg/15 mg, 40 mg/20 mg
These tablets are for oral use. You should take [Product Name] with sufficient liquid (½ glass of water). The tablet can be divided into equal doses but must not be chewed or crushed. The tablet may be taken with or without food.

Take [Product Name] 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).

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

If you take more [Product Name] than you should
If you have taken more than the prescribed dose of [Product Name] 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 [Product Name]
If you forget to take [Product Name] or if you take a dose lower than the one prescribed, you may not feel any effect.

If you 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 [Product Name]
Do not stop your treatment with [Product Name] 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 have been seen in patients being treated for pain:

Common (may affect up to 1 in 10 people)
- abdominal pain
- constipation
- diarrhoea
- dry mouth
- indigestion
- vomit (be sick)
- feel sick
- flatulence (wind)
- decreased appetite up to loss of appetite
- a feeling of dizziness or 'spinning'
- headache
- hot flushes
- a feeling of unusual weakness

- tiredness or exhaustion
- itchy skin
- skin reactions/rash
- sweating
- vertigo
- difficulty in sleeping
- drowsiness

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

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

Not known (frequency cannot be estimated from the available data)
- euphoric mood
- severe drowsiness
- erectile dysfunction
- nightmares
- hallucinations
- shallow breathing
- difficulties in passing urine
- aggression
- tingling skin (pins and needles)
- belching
- problems with breathing during sleep (sleep apnoea syndrome), for more information see section 2 'Warnings and precautions'

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, a feeling of extreme happiness)
- decreased activity
- increased activity
- difficulties in passing urine
- hiccups

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

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

- bleeding gums

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

The following side effects have been seen in patients being treated for restless legs syndrome:

Very common (may affect more than 1 in 10 people)
- headache
- drowsiness
- constipation
- feel sick
- sweating
- tiredness or exhaustion

Common (may affect up to 1 in 10 people)
- decreased appetite up to loss of appetite
- difficulty sleeping
- depression
- a feeling of dizziness or 'spinning'
- difficulties to concentrate
- shaking
- tingling in hands or feet
- vision impairment
- vertigo
- hot flushes
- drop in blood pressure
- rise in blood pressure
- abdominal pain
- dry mouth
- vomit (be sick)
- hepatic enzymes increased (alanine aminotransferase increased, gamma glutamyltransferase increased)
- itchy skin
- skin reactions/rash
- chest pain
- chills
- pain
- thirst

Uncommon (may affect up to 1 in 100 people)
- reduced sexual drive
- episodes of suddenly falling asleep
- altered taste
- difficulties breathing
- wind
- erectile dysfunction
- withdrawal symptoms such as agitation
- swelling of hands, ankles or feet
- injuries from accidents

Not known (frequency cannot be estimated from available data)

- hypersensitivity/ allergic reactions
- abnormal thoughts
- anxiety
- confusion
- nervousness
- restlessness
- euphoric mood
- hallucinations
- nightmares
- epileptic seizures (especially in persons with epileptic disorder or predisposition to seizures)
- drug dependence
- severe drowsiness
- impaired speaking
- fainting
- chest tightness especially if you already have coronary heart disease
- palpitations
- increase in pulse rate
- shallow breathing
- cough
- runny nose
- yawning
- abdominal bloating
- diarrhoea
- aggression
- indigestion
- belching
- dental changes
- biliary colic
- muscle cramps
- muscle twitches
- muscle pain
- difficulties passing urine
- increased urge to urinate
- generally feeling unwell
- weight loss
- weight increase
- a feeling of unusual weakness
- lack of energy

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Product Name]

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, label and 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.

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 [Product Name] contains
The active substances are oxycodone hydrochloride and naloxone hydrochloride.

[Product Name] 5 mg/2.5 mg
Each prolonged-release tablet contains 5 mg oxycodone hydrochloride (equivalent to 4.5 mg oxycodone) and 2.5 mg naloxone hydrochloride (as 2.74 mg naloxone hydrochloride dihydrate equivalent to 2.25 mg naloxone).

[Product Name] 10 mg/5 mg
Each prolonged-release tablet contains 10 mg oxycodone hydrochloride (equivalent to 9 mg oxycodone) and 5 mg naloxone hydrochloride (as 5.45 mg naloxone hydrochloride dihydrate equivalent to 4.5 mg naloxone).

[Product Name] 20 mg/10 mg
Each prolonged-release tablet contains 20 mg oxycodone hydrochloride (equivalent to 18 mg oxycodone) and 10 mg naloxone hydrochloride (as 10.9 mg naloxone hydrochloride dihydrate equivalent to 9 mg naloxone).

[Product Name] 30 mg/15 mg
Each prolonged-release tablet contains 30 mg oxycodone hydrochloride (equivalent to 27 mg oxycodone) and 15 mg naloxone hydrochloride (as 16.35 mg naloxone hydrochloride dihydrate equivalent to 13.5 mg naloxone).

[Product Name] 40 mg/20 mg
Each prolonged-release tablet contains 40 mg oxycodone hydrochloride (equivalent to 36 mg oxycodone) and 20 mg naloxone hydrochloride (as 21.8 mg naloxone hydrochloride dihydrate equivalent to 18 mg naloxone).

The other ingredients are:

Tablet core
Polyvinyl acetate, povidone, sodium laurilsulfate, silica, colloidal anhydrous, cellulose, microcrystalline and magnesium stearate.

Tablet coating
[Product Name] 5 mg/2.5 mg
Polyvinyl alcohol, titanium dioxide (E171), macrogol and talc.

[Product Name] 10 mg/5 mg
Polyvinyl alcohol, titanium dioxide (E171), macrogol, talc and iron oxide red (E172).

[Product Name] 20 mg/10 mg
Polyvinyl alcohol, titanium dioxide (E171), macrogol and talc.

[Product Name] 30 mg/15 mg
Polyvinyl alcohol, titanium dioxide (E171), macrogol, talc and iron oxide yellow (E172).

[Product Name] 40 mg/20 mg
Polyvinyl alcohol, titanium dioxide (E171), macrogol, talc and iron oxide red (E172).

What [Product Name] looks like and contents of the pack
[Product Name] 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.

[Product Name] 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.

[Product Name] 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.

[Product Name] 30 mg/15 mg
Yellow, oblong, biconvex prolonged-release tablet with break scores on both sides, with a length of 12.2 mm, a width of 5.7 mm and a height of 3.3 - 4.3 mm.
The tablet can be divided into equal doses.

[Product Name] 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.

[Product Name] is available in:
Child-resistant blisters of 10, 14, 20, 28, 30, 50, 56, 60, 90, 98 and 100 prolonged-released tablets; child-resistant perforated unit-dose blisters of 10x1, 14x1, 20x1, 28x1, 30x1, 50x1, 56x1, 60x1, 90x1, 98x1 and 100x1 prolonged-release tablets or bottles with a child-resistant closure containing 50, 100, 200 or 250 prolonged-released tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

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

Bulgaria:	Оксикодон/Налоксон Тева10 mg/5 mg, 20 mg/10 mg таблетки с удължено освобождаване
Croatia:	Oksikodon/nalokson Pliva 5 mg/2.5 mg; 10 mg/5 mg; 20 mg/10 mg; 30 mg/15 mg; 40 mg/20 mg tablete s produljenim oslobađanjem
Finland:	Oxycodone/Naloxone ratiopharm 5/2,5, 10/5, 20/10, 30/15, 40/20mg depottabletti
Germany:	Oxycodon comp.-AbZ 5 mg/2,5 mg, 10 mg/5 mg, 20 mg/10 mg, 30 mg/15 mg, 40 mg/20 mg Retardtabletten
Italy:	Noxidol 5mg/2,5mg, 10mg/5mg, 20mg/10mg, 30mg/15mg, 40mg/20mg
Poland:	Oxyduo
Slovakia:	Oxykodon/Naloxon Teva 5 mg/2,5mg, 10 mg/5 mg, 30 mg/15mg, 20 mg/10 mg, 40 mg/20 mg tablety s predĺženým uvoľňovaním
Spain:	Oxicodona/Naloxona Teva 5/2.5, 10/5, 20/10, 30/15, 40/20mg comprimidos de liberación prolongada
Sweden:	Oxycodone/Naloxone Teva
United Kingdom (Northern Ireland):	Tarim 5mg/2.5 mg, 10 mg/5 mg, 20 mg/10 mg, 30 mg/15 mg, 40 mg/20 mg Prolonged-release Tablets

This leaflet was last revised in {month YYYY}
[To be completed nationally]

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APPROVALS

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Poonam Thanekar	Regulatory Affairs Approval	28-Sep-2021 04:57:36 AM