Package leaflet: Information for the patient

Ixyldone 15mg Prolonged-Release Tablets
Ixyldone 20mg Prolonged-Release Tablets
Ixyldone 30mg Prolonged-Release Tablets
Ixyldone 40mg Prolonged-Release Tablets
Ixyldone 60mg Prolonged-Release Tablets
Ixyldone 80mg 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:

1. What Ixyldone is and what it is used for

Ixyldone is a strong acting painkiller (analgesic) and belongs to the group of opioids.
Ixyldone is used to treat severe pain, which can be adequately managed only with opioid analgesics. Ixyldone is indicated in adults and adolescents aged 12 years and older.

2. What you need to know before you take Ixyldone

Do not take Ixyldone
- if you are allergic to oxycodone hydrochloride or any of the other ingredients of this medicine (listed in section 6),
- if your breathing is not sufficient; that means significantly shallow or slowed down (severe respiratory depression)
- if you suffer from severe chronic obstructive lung disease associated with obstruction of the airways (COPD)
- if you suffer from cor pulmonale (heart problems after long term lung disease)
- if you suffer from severe bronchial asthama
- if you suffer from intestinal paralysis, a condition in which the intestine has stopped working (paralytic ileus)

Warnings and precautions
Talk to your doctor or pharmacist before taking Ixyldone
- if you are older or debilitated,
- if you have severe lung problem
- if your liver or kidney function is impaired
- if you have a thyroid disease where the skin on the face and limbs is pasty, swollen, cool and dry,
- if your thyroid produces an insufficient amount of hormones (called underactive thyroid or

hypothyroidism)
- if you have Addison's disease
- if you have enlarged prostate gland, which causes difficulty in passing urine
- if you suffer with psychosis caused by alcohol or have a mental disorder as a result of an infection (toxic psychosis)
- if you are an alcoholic
- if you are or have ever been addicted to alcohol or drugs, or have a known opioid-dependence
- if you have or had a dependency on strong painkillers (opioids)
- if you have inflammation of the pancreas (which causes severe pain in the abdomen and back), problems with your gall bladder or bile duct
- if you have colicky abdominal pain or discomfort
- if you have an obstructive or inflammatory bowel disorder
- if your doctor suspects that you have intestinal paralysis (a condition where your bowel has stopped working)
- if you have a severe headache or feel sick as this may indicate that the pressure in your skull is increased
- if you suffer from disturbances of circulatory regulation
- if you suffer from epilepsy or have a seizure tendency
- if you take medicines for the treatment of depression (MAO inhibitors), e.g. tranylcypromine, phenelzine, isocarboxazid, moclobemide or linezolid, or you have taken this type of medicine in the last two weeks
- if you or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction")
- if you are a smoker
- if 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

Do not use for short-term post-operative pain owing to the increased risk of dependence and breathlessness

If you are going to have an operation, or have just had an operation, please tell the doctor at the hospital if you are taking Ixyldone. Your doctor may adjust your dose.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

Tolerance, dependence and addiction

This medicine contains oxycodone, which is an opioid. It can cause dependence and/or addiction.

This medicine contains oxycodone which is an opioid medicine. Repeated use of opioid painkillers can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Ixyldone may lead to dependence, abuse and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it. You might feel that you need to carry on taking your medicine, even when it doesn't help to relieve your pain.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent or addicted on Ixyldone if:

- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").
- You are a smoker.
- 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.

If you notice any of the following signs whilst taking Ixyldone, it could be a sign that you have become dependent or addicted.
– You need to take the medicine for longer than advised by your doctor
– You need to take more than the recommended dose
– You are using the medicine for reasons other than prescribed, for instance, 'to stay calm' or 'help you sleep'
– You have made repeated, unsuccessful attempts to quit or control the use of the medicine
– When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again ('withdrawal effects')

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop taking Ixyldone).

Sleep-related breathing disorders
Ixyldone 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.

Talk to your doctor if any of these conditions apply to you.

The most significant risk of overdose of opioids is slow and shallow breathing (respiratory depression). This is most likely to occur in elderly and debilitated patients and may also cause a drop in blood pressure. This could lead to e.g. fainting.

This medicine has been specially formulated to release the active substance over a 12-hour period. Ixyldone prolonged-release tablets are not allowed to be divided, chewed or crushed. This would lead to a potentially lethal dose of the active substance oxycodone hydrochloride (see under "If you take more Ixyldone tablets than you should or if someone accidentally swallows your tablets").

When used for a long time (chronic) tolerance to the effects may appear and you may require progressively higher doses of Ixyldone to maintain pain control. Do not change the dosage without consulting your doctor.
For pain not related to cancer, opioids are not the drug of first choice and are not recommended as the only treatment. Other medicines should be used together with opioids in the treatment of chronic pain. Your doctor should monitor you closely and make any necessary adjustments to your dose while you are taking Ixyldone to prevent addiction and abuse.

Prolonged use of Ixyldone may lead to physical dependence. If treatment is stopped abruptly, withdrawal symptoms may occur such as yawning, abnormal dilation of the pupils, tear disorder, runny nose, shaking, sweating, anxiety, convulsions, difficulty sleeping or muscle pain. When you no longer require therapy with Ixyldone, it may be advisable for your doctor to taper the dose gradually.

The active substance oxycodone hydrochloride, similar to other strong opioids (strong painkillers) has a primary dependence potential.

Developing psychological dependence may be possible. In cases of present or past abuse of alcohol or medicines, Ixyldone must be used with special caution only.

Especially in high dosages you may experience increased sensitivity to pain (hyperalgesia) despite the fact that you are taking increasing doses of Ixyldone. Your doctor will decide whether you need a change in dose or a change in strong analgesic (opioids).
Ixyldone are for oral use only (swallowing of whole tablets). The prolonged release tablets should not be dissolved and injected, as this can cause serious, possibly fatal consequences.

If you are going to have an operation, please tell the doctor at the hospital that you are taking Ixyldone. Similar to other opioids, oxycodone can affect the normal production of the body's hormones (such as cortisol or sex hormones). This happens especially if you have received high doses over long periods of time.

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

Children (under 12 years of age)
Safety and efficacy have not been established in children under 12 years of age. Therefore, Ixyldone is not recommended in children under 12 years of age.

Anti-doping warning
The use of Ixyldone may lead to positive results in doping controls. Use of Ixyldone as a doping agent may become a health hazard.

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

Use of opioids including Ixyldone and sedative medicines such as benzodiazepines or related drugs together 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 Ixyldone 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.

Side effects of Ixyldone may occur more frequent or more severe if you use Ixyldone concomitantly with medicines that may interfere with the brain function or are used to treat allergies, motion sickness or vomiting. Side effects may occur e.g. flattening and slowing down of breathing (respiratory depression), constipation, dry mouth or disorders in urination. 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, and body temperature above 38°C. Contact your doctor when experiencing such symptoms.

Please tell your doctor or pharmacist if you are taking any of the following medicines:

- medicines to help you sleep or stay calm (for example tranquillisers, hypnotics or sedatives including benzodiazepines)
- medicines to treat depression (for example paroxetine or amitriptyline) including those medicines belonging to the group of MAO-inhibitors (such as tranylcypromine,

phenelzine, isocarboxazid, moclobemide or linezolid)
- medicines for allergies, motion sickness or vomiting (antihistamines, antiemetics)
- medicines to treat psychiatric or mental disorders (such as psychotropic drugs, phenothiazines or neuroleptic drugs) medicines for the treatment of epilepsy, pain and anxiety, such as gabapentin and pregabalin
- muscle relaxants for the treatment of muscle cramps (such as tizanidine)
- medicines to treat Parkinson's disease
- other strong acting painkillers (opioids)
- cimetidine (a medicine for stomach ulcers, indigestion or heartburn)
- medicines to treat fungal infections (such as ketoconazole, voriconazole, itraconazole, or posaconazole)
- medicines used to treat infections (such as clarithromycin, erythromycin or telithromycin)
- medicines from the group of protease inhibitors to treat HIV (such as boceprevir, ritonavir, indinavir, nelfinavir or saquinavir)
- rifampicin to treat tuberculosis
- carbamazepine (a medicine to treat epilepsy or seizures, and certain pain conditions)
- phenytoin (a medicine to treat seizures, fits or convulsions)
- the medical plant St John's Wort (also known as Hypericum perforatum)
- quinidine (medicine to treat cardiac arrhythmias)
- certain medicines to prevent your blood clotting or to help thin your blood (e.g. phenprocoumon)

Ixyldone with food, drink and alcohol
Drinking alcohol whilst taking Ixyldone may make you feel more sleepy and 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 Ixyldone. While taking Ixyldone you should avoid drinking grapefruit juice.

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 use Ixyldone if you are pregnant. There are limited data from the use of oxycodone in humans during pregnancy.
Prolonged use of oxycodone during pregnancy can cause withdrawal symptoms in the newborn. Use of oxycodone during childbirth can cause shallow and slowed down breathing (respiratory depression) in your newborn.

Breast-feeding
You should not take Ixyldone if you are breast-feeding as the active substance oxycodone may pass in the breast milk and cause sedation and shallow and slowed down breathing (respiratory depression) in the breast-fed child.

Driving and using machines
Ixyldone may impair the ability to drive or operate machinery. This is particularly likely at the beginning of therapy with Ixyldone, after increasing the dose, after a change of the medicinal preparation as well as the interaction of Ixyldone with alcohol or medicinal products which may impair brain function.

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

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive while you have this medicine in your body over a specified limit unless you have a defence (called the 'statutory defence').
- This defence applies when:
    - The medicine has been prescribed to treat a medical or dental problem and
    - You have taken it according to the instructions given by the prescriber and in the information provided with the medicine
    - Please note that it is still an offence to drive if you are unfit because of the medicine (i.e. your ability to drive is being affected).

Details regarding a new driving offence concerning driving after drugs have been taken in the UK may be found here: https://www.gov.uk/drug-driving-law.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Ixyldone contains lactose
These tablets contain lactose which is a form of sugar. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking Ixyldone.

3. How to take Ixyldone

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

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Ixyldone, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also if you stop taking Ixyldone).

Dosage
Your doctor will determine how much Ixyldone you should take and how the total daily dose should be divided. Your doctor will adjust the dose to the intensity of the pain and to your individual sensitivity. Do not change the dosage without consulting your doctor.

You should receive the lowest effective dose sufficient to relieve your pain. If you have been treated with opioids before, it may be possible that your doctor may start treatment at higher doses. A gradual increase of the dose may be necessary if pain relief is insufficient or the pain level increases.

Please talk to you doctor if you suffer from intermittent pain (breakthrough pain) despite pain therapy. Your doctor may prescribe you an additional analgesic (non-sustained analgesic) to treat breakthrough pain or adjust your dosage with Ixyldone. Ixyldone is not intended for the treatment of breakthrough pain.

Adults and adolescents (12 years of age and older)
Ixyldone prolonged release tablets are available in 5 mg, 10 mg, 15 mg, 20 mg, 30 mg 40 mg, 60 mg and 80 mg strengths.

The usual initial dose is 10 mg oxycodone hydrochloride in 12 hourly intervals.

For the treatment of non cancer pain a daily dose of 40 mg of oxycodone hydrochloride is generally a sufficient daily dose, 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.

Some patients taking Ixyldone on a fixed schedule require fast-release painkillers as an on-demand medication to manage breakthrough pain. Ixyldone prolonged-release tablets are not intended for the treatment of this breakthrough pain.

Elderly patients
In elderly patients without liver or kidney problems, dosage adjustment is usually not necessary.

Patients with liver or kidney problems
If you suffer from liver or kidney problems and you have not received opioids before, you should receive an initial dose of half of the recommended adult dose.

Other risk patients
If your body weight is low or you have a slower metabolisation rate, and have not taken opioids before, you should initially receive half of the recommended adult dose.

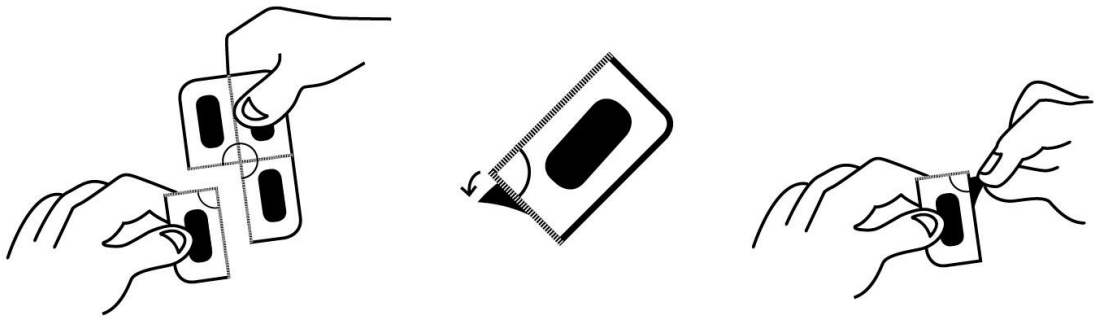
Method of administration

Oral use
Swallow the prolonged-release tablet 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.).

You can take Ixyldone with or without food.

Swallow the prolonged-release tablets as a whole, so that the special prolonged release properties are not affected over a longer period of time. The prolonged-release tablets must be swallowed whole and must not be broken, divided, chewed or crushed.

Opening instructions:
This medicinal product is in childproof packaging. The prolonged-release tablets cannot be pressed out of the blister. Please observe the following instructions when opening the blister.



1. Pull off a single dose by tearing along the perforated line on the blister.
2. An unsealed area is exposed/can be reached by this; this area is at the point where the perforated lines intersect with each other.
3. At the unsealed flap, peel away the cover foil from the bottom foil.

Duration of use
Your doctor will tell you how long you should take Ixyldone.

Do not stop taking Ixyldone without consulting your doctor (see ‘if you stop taking Ixyldone’).

If you are taking Ixyldone for a long period of time, your treatment should be monitored and discussed

regularly with your doctor. This is necessary in order to achieve the best pain therapy possible as well as to be able to treat any occurring side effects, to allow a decision on dose adjustment and to decide whether treatment should be continued.

If you feel that the effect of Ixyldone is too strong or too weak, talk to your doctor or pharmacist.

If you take more Ixyldone than you should or someone accidentally swallows your tablets
If you have taken more Ixyldone than prescribed or someone else has accidentally swallowed your tablets, you should inform your doctor immediately.

Overdose may cause:
• narrowed pupils (miosis),
• flattening and slowing down of breathing (respiratory depression),
• somnolence progressing up to stupor (anaesthesia like condition),
• decreased tension of skeletal muscles,
• slowed pulse rate,
• drop in blood pressure
• a brain disorder (known as toxic leukoencephalopathy)

Loss of consciousness (coma), water retention in the lung and circulatory collapse may occur in more severe cases and may lead to death. Never engage in situations which require a high degree of concentration such as driving.

If you forget to take Ixyldone
If you use a smaller dose of Ixyldone than prescribed or you miss the intake of a dose, this may result in insufficient pain relief.

You can make up for a forgotten dose if the next regular intake is not due for at least another 8 hours. If the time to the next dose is shorter, take the missed dose and take the next dose 8 hours later. You can then continue to take this medicine as directed.

In principle, you should not take Ixyldone more than once every 8 hours. Please ask your doctor or pharmacist if you are not sure. Never take a doubled amount of a single dose.

If you stop taking Ixyldone
Do not stop treatment without informing your doctor.
If you stop taking Ixyldone it may lead to withdrawal symptoms (e.g. yawning, dilated pupils, lacrimation, runny nose, tremors, sweating, anxiety, agitation, seizures, insomnia or muscular pains). Therefore, it may be advisable that your doctor gradually reduces the dose.

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. As with other strong analgesics or painkillers, there is a risk that you may become addicted to Ixyldone.

If you experience any of the following significant side effects listed below, stop taking Ixyldone and contact your doctor immediately.

- Suddenly occurring breathing problems, swelling of the eyelids, face or lips, rash and itching, especially on the whole body – these are signs of severe allergic reactions.
- Slow and depressed breathing (respiratory depression) – this mainly occurs if you are older and debilitated or if you have taken too much Ixyldone.

- Severe drop in blood pressure – this may lead to dizziness and fainting (syncope).
- Narrowing of the pupils, cramping of the bronchial muscles (leads to breathlessness) or depression of the cough reflex.

Other possible side effects

Very common (may affect more than 1 in 10 people):
- constipation – this side effect can be counteracted by preventative measures (such as increased drinking, nutrition rich in fibre)
- vomiting, nausea – especially at the start of treatment. If you experience nausea or vomiting, your doctor may prescribe medication for you
- tiredness to drowsiness (sedation)
- dizziness
- headache.

Common (may affect up to 1 in 10 people):
- pain
- diarrhoea
- dry mouth
- hiccups
- indigestion
- decreased
- appetite up to loss of appetite
- altered mood and personality
- confusion
- depression
- decreased activity
- restlessness
- increased activity
- nervousness
- difficulty in sleeping
- abnormal thinking
- muscle tremors
- lethargy
- skin reactions/rash
- sweating
- pain in urination
- increased urge to urinate
- a feeling of unusual weakness, tiredness or fatigue
- anxiety
- shortness of breath
- abdominal pain or discomfort

Uncommon (may affect up to 1 in 100 people):
- withdrawal symptoms
- need to take higher doses of Ixyldone to achieve the desired pain relief (tolerance development)
- injuries from accidents
- allergic reactions (hypersensitivity)
- loss of body water (dehydration)
- hyperexcitability, mood swings, a feeling of extreme happiness
- perception disturbances (e.g. hallucinations, derealisation)

- decreased sexual drive
- epileptic convulsions (especially in people with epilepsy or a tendency to seizures)
- loss of memory, concentration impaired, migraine
- increased muscle tension
- involuntary muscle contractions
- numbness
- abnormal coordination
- difficulty in speaking
- tingling of skin
- taste disorder
- visual impairment
- hearing impaired
- a feeling of dizziness or 'spinning'
- a fast heartbeat, palpitations
- enlarged blood vessels
- vocal changes (dysphonia)
- cough
- oral ulcers
- inflammation of the oral mucosa
- difficulty in swallowing
- wind
- belching
- intestinal paralysis (a condition where the bowel does not work properly
- increased hepatic enzymes
- dry skin
- inability to fully empty the bladder (urinary retention)
- erectile disorder
- decreased concentration of sex hormones affecting the sperm production in
- men or cycle of menstrual period in women
- chills
- pain (e.g. chest pain)
- malaise
- water retention (oedema, e.g. in hands, ankles or legs, especially at the ankles)
- thirst.

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

- feeling of faintness, especially on standing up
- dark coloured or tarry stools
- dental changes
- bleeding gums
- infections such as cold sores or herpes (which may cause blisters around the mouth or genitals)
- increased appetite
- hives (urticaria)
- weight increase or decrease.

Frequency not known (frequency cannot be estimated from the available data)

- aggression,
- increased sensibility to pain
- dental caries,
- biliary stasis,
- biliary colic,
- absence of menstrual bleeding

- withdrawal symptoms in new-borns whose mother used Ixyldone during pregnancy
- sleep apnoea (breathing pauses during sleep)
- a problem affecting a valve in the intestines that may cause severe upper abdominal pain (sphincter of Oddi dysfunction)

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 Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ixyldone

Keep this medicine out of the sight and reach of children. Store this medicine in a locked safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.

Do not use this medicine after the expiry date which is stated on the blister and the carton after "EXP". The expiry date refers to the last day of that month.

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. Content of the pack and other information

What Ixyldone contains

The active substance is oxycodone hydrochloride.

15 mg:
Each prolonged-release tablet contains 15 mg oxycodone hydrochloride corresponding to 13.5 mg oxycodone.
The other ingredients are:
Tablet core: Lactose monohydrate, ammonio methacrylate copolymer Type B dispersion 30%, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate.
Tablet coating: Hypromellose, talc, macrogol 400, titanium dioxide (E171), iron oxide black (E172).

20 mg:
Each prolonged-release tablet contains 20 mg oxycodone hydrochloride corresponding to 17.9 mg oxycodone.
The other ingredients are:
Tablet core: Lactose monohydrate, ammonio methacrylate copolymer Type B dispersion 30%, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate.
Tablet coating: Hypromellose, talc, macrogol 400, titanium dioxide (E171), iron oxide red (E172).

30 mg:
Each prolonged-release tablet contains 30 mg oxycodone hydrochloride corresponding to 26.9 mg oxycodone.
The other ingredients are:
Tablet core: Lactose monohydrate, ammonio methacrylate copolymer Type B dispersion 30%, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate.
Tablet coating: Hypromellose, talc, macrogol 400, titanium dioxide (E171), iron oxide brown (E172), iron oxide black (E172).

40 mg:
Each prolonged-release tablet contains 40 mg oxycodone hydrochloride corresponding to 35.9 mg oxycodone.
The other ingredients are:
Tablet core: Lactose monohydrate, ammonio methacrylate copolymer Type B dispersion 30%, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate.
Tablet coating: Hypromellose, talc, macrogol 400, titanium dioxide (E171), iron oxide red (E172), iron oxide yellow (E172).

60 mg:
Each prolonged-release tablet contains 60 mg oxycodone hydrochloride corresponding to 53.8 mg oxycodone.
The other ingredients are:
Tablet core: Lactose monohydrate, ammonio methacrylate copolymer Type B dispersion 30%, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate.
Tablet coating: Hypromellose, talc, macrogol 400, titanium dioxide (E171), iron oxide red (E172), erythrosine (E127).

80 mg:
Each prolonged-release tablet contains 80 mg oxycodone hydrochloride corresponding to 71.7 mg oxycodone.
The other ingredients are:
Tablet core: Lactose monohydrate, ammonio methacrylate copolymer Type B dispersion 30%, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate.
Tablet coating: Hypromellose, macrogol 400, titanium dioxide (E171), indigo carmine aluminum lake (E132), iron oxide yellow (E172).

What Ixyldone looks like and contents of the pack
Ixyldone 15 mg prolonged-release tablets:
Grey, round, biconvex, prolonged-release tablets with a diameter of 6.9 – 7.3 mm and a height of 3.2 - 3.9 mm.

Ixyldone 20 mg prolonged-release tablets:
Light pink, round, biconvex, prolonged-release tablets with a diameter of 6.9 – 7.3 mm and a height of 3.2 -3.9 mm.

Ixyldone 30 mg prolonged-release tablets:
Brown, round, biconvex, prolonged-release tablets with a diameter of 6.9 – 7.3 mm and a height of 3.2 -3.9 mm.

Ixyldone 40 mg prolonged-release tablets:
Light orange to ochre, round, biconvex, prolonged-release tablets with a diameter of 6.9 – 7.3 mm and a height of 3.2 -3.9 mm.

Ixyldone 60 mg prolonged-release tablets:
Pink-red, round, biconvex, prolonged-release tablets with a diameter of 8.6 – 9.0 mm and a height of 4.6 -5.3 mm.

Ixyldone 80 mg prolonged-release tablets:
Green, round, biconvex, prolonged-release tablets with a diameter of 8.6 – 9.0 mm and a height of 5.0 – 5.6 mm.

Ixyldone is available for 10, 14, 20, 25, 28, 30, 40, 50, 56, 60, 98 and 100 prolonged-release tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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