PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

MORNINGSIDE HEALTHCARE

Ixyldone

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

Oxycodone hydrochloride

This medicine contains oxycodone hydrochloride which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

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

This medicine has been prescribed for you for treating severe pain, which can be adequately managed only with opioid analgesics. It contains the oxycodone hydrochloride which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to you and should not be given to anyone else.

Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

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 you suffer from severely depressed breathing (respiratory depression) with too little oxygen in the blood (hypoxia) and/or too much carbon dioxide (hypercapnia) in the blood,
- if you suffer from severe chronic obstructive lung disease, cor pulmonale (cardiac changes due to chronic overload of lung circulation) or acute, severe bronchial asthma,
- if you suffer from intestinal paralysis (paralytic ileus),
- if you have an acute abdomen or suffer from a delayed gastric emptying.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ixyldone

- if you are older or debilitated,
- if your lung, liver or kidney function is severely impaired,
- if you suffer from myxoedema (certain illnesses of the thyroid gland), impaired function of the thyroid gland,
- if you suffer from adrenal insufficiency (Addison's disease),
- if you suffer from enlargement of the prostate (prostatic hypertrophy),
- if you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs,
- if you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs,
- if you feel you need to take more of Ixyldone to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever,
- if you suffer from inflammatory bowel disorders,
- if you suffer from inflammation of the pancreas (pancreatitis),
- in conditions with increased brain pressure,
- if you suffer from disturbances of circulatory regulation,
- if you suffer from colic of the bile duct and ureter,
- if you suffer from epilepsy or have a seizure tendency,
- if you take MAO inhibitors (for the treatment of depression).

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

Dependence and tolerance

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Ixyldone are for oral use only. In case of abusive injection (injection in a vein) the tablet excipients (especially talc) may lead to destruction (necrosis) of the local tissue, change of lung tissue (granulomas of the lung) or other serious, potentially fatal events.

Anti-doping warning

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

Children and adolescents

Oxycodone has not been investigated in children under 12 years. Safety and efficacy have not been established therefore use in children under 12 years of age is not recommended.

Other medicines and Ixyldone

Tell your doctor or pharmacist if you are taking, have recently taken any other medicines, including medicines obtained without a prescription. If you take these tablets with some other medicines, the effect of these tablets or the other medicine may be changed.

The tablets must not be used together with a monoamine oxidase inhibitor, or if you have taken this type of medicine in the last two weeks (see section 2 'Do not take...').

Tell your doctor or pharmacist if you are taking:

- medicines to help you sleep or stay calm (for example tranquillisers, hypnotics or sedatives)
- medicines to treat depression (for example paroxetine)
- medicines to treat psychiatric or mental disorders (such as phenothiazines or neuroleptic drugs)
- other strong analgesics ('painkillers')
- muscle relaxants
- quinidine (a medicine to treat a fast heartbeat)
- 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)
- a specific type of medicine known as a protease inhibitor to treat HIV (examples include boceprevir, ritonavir, indinavir, nelfinavir or saquinavir)
- rifampicin to treat tuberculosis
- carbamazepine (a medicine to treat seizures, fits or convulsions and certain pain conditions)
- phenytoin (a medicine to treat seizures, fits or convulsions)
- a herbal remedy called St John's Wort (also known as Hypericum perforatum).

Also, tell your doctor if you have recently been given an anaesthetic.

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 Ixyldone 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 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.

Ixyldone with food, drink and alcohol

Drinking alcohol whilst taking Ixyldone 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 Ixyldone.

You should avoid drinking grapefruit juice during your treatment with Ixyldone.

Pregnancy and breast-feeding

Pregnancy

Do not take Ixyldone if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Ixyldone during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Breast-feeding

Do not take Ixyldone while you are breast-feeding as oxycodone hydrochloride passes into breast milk and will affect your baby.

Driving and using machines

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 or in the information provided with the medicine and
  - It was not affecting your ability to drive safely.

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.

Oxycodone hydrochloride impairs alertness and reactivity to such an extent that the ability to drive and operate machinery is affected or ceases altogether. To look at the possible side effects affecting the motor skills and concentration (see section 4).

With stable therapy, a general ban on driving a vehicle may be not necessary. The treating physician must assess the individual situation. Please discuss with your doctor whether or under what conditions you can drive a vehicle.

Ixyldone contains lactose

If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.

3. How to take Ixyldone

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

Your prescriber should have discussed with you, how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

The recommended dose is:

Adults and adolescents (12 years of age and older)

The usual initial dose is 10 mg oxycodone hydrochloride in 12 hourly intervals. However, your doctor will prescribe the dose required to treat pain.

Patients who have already taken opioids can start treatment with higher dosages taking into account their experience with opioid treatment.

For the treatment of non cancer pain a daily dose of 40 mg of oxycodone hydrochloride is generally sufficient, but higher dosages may be necessary.

Patients with cancer pain usually require dosages from 80 to 120 mg of oxycodone hydrochloride which may be increased up to 400 mg in individual cases.

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

Risk patients

If you have impaired kidney and/or liver function or if you have a low body weight your doctor may prescribe a lower starting dose.

Use in children and adolescents

Ixyldone is not recommended in children younger than 12 years of age.

Method of administration

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.).

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

The prolonged-release tablets may be taken with or independent of meals with a sufficient amount of liquid.

Ixyldone should not be taken with alcoholic beverages.

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.

Further determination of the daily dose, the division into the single doses and any dose adjustments during the

further course of therapy are performed by the treating physician and depend on the previous dosage.

Some patients who receive Ixyldone according to a fixed schedule need rapidly acting painkillers as rescue medication to control breakthrough pain. Ixyldone is not intended for the treatment of breakthrough pain.

The treatment needs to be controlled regularly with regard to pain relief and other effects in order to achieve the best pain therapy possible as well as to be able to treat any occurring side effects in good time and to decide whether treatment should be continued.

If you take more Ixyldone than you should

If you have taken more Ixyldone as prescribed you should inform your doctor or your local poison control center immediately. The following symptoms may occur: constricted pupils (miosis), depressed breathing (respiratory depression), drowsiness, skeletal muscle flaccidity and drop in blood pressure. In severe cases circulatory collapse, mental and motor inactivity (stupor), unconsciousness (coma) slowing of the heart rate and accumulation of water in the lungs (non-cardiogenic lung oedema) may occur; abuse of high doses of strong opioids such as oxycodone can be fatal. In no case you should expose yourself to situations requiring elevated concentration e.g. driving a car.

If you forget to take Ixyldone

If you use a smaller dose of Ixyldone than directed or you miss the intake of a dose, pain relief will consequently be insufficient or cease altogether.

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

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

Do not take a double dose to make up for a forgotten dose.

If you stop taking Ixyldone

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

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.

Significant side effects or signs to consider and measures to be taken when these side effects or signs occur:

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

Depressed breathing is the most significant risk induced by opioids and is most likely to occur in elderly or debilitated patients. As a consequence, in predisposed patients opioids can cause severe drops in blood pressure.

Apart from this oxycodone can cause constricted pupils, bronchial spasms and spasms in smooth muscles and suppress the cough reflex.

Other possible side effects

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

- Sedation (tiredness to drowsiness); dizziness; headache; constipation; nausea; vomiting; itching.

Common (may affect up to 1 in 10 people):

- Several psychological side effects such as changes in mood (e.g. anxiety, depression); changes in activity (mostly sedation, sometimes accompanied by lethargy, occasionally increase with nervousness and sleep disorders) and changes in performance (thought process disorder, confusion, isolated cases of speech disorders),
- feeling weak (asthenia); trembling (tremor),
- depressed breathing, difficulty in breathing or wheezing (dyspnoea, bronchospasm),
- dry mouth, rarely accompanied by thirst and difficulty swallowing; gastrointestinal disorders such as bellyache; diarrhoea; upset stomach (dyspepsia); loss of appetite,
- skin disorders such as rash, rarely increased sensitivity to light (photosensitivity), in isolated cases itchy (urticaria) or scaly rash (exfoliative dermatitis),
- urinary disorders (frequent urination), increased sweating (hyperhidrosis),
- lack of strengths (asthenic conditions).

Uncommon (may affect up to 1 in 100 people):

- A condition which causes abnormal production of a hormone reducing urination (syndrome of inappropriate antidiuretic hormone secretion),
- change in perception such as depersonalisation, hallucinations (perception of things that are not there), emotional instability, change in taste, visual disturbances, abnormally acute sense of hearing (hyperacousis); euphoria; restlessness,
- increased and decreased muscle tone involuntary muscle contractions,
- disturbance of memory (amnesia); fits, speech disorder; reduced sense of touch (hypaesthesia); coordination disturbances; feeling unwell; fainting; pins and needles (paraesthesia); feeling of spinning (vertigo),
- accelerated pulse; fast or irregular beating of the heart (supraventricular tachycardia, palpitations (in context of withdrawal syndrome), widening of the blood vessels (vasodilatation),
- increased coughing; inflammation of the throat (pharyngitis); runny nose; voice changes, oral ulcers; inflammation of the gums, inflamed mouth (stomatitis); impaired ability to swallow (dysphagia), flatulence, belching; obstruction in the gut (ileus), taste disturbance,
- increased liver values,
- dry skin,
- urinary retention,
- disturbances of sexual function (reduced sexual desire and impotence),
- accidental injuries; pain (e.g. chest pain); excessive fluid in the tissues (oedema); migraine;
- physical dependence with withdrawal symptoms; allergic reactions,
- lack of water in the body (dehydration),
- hypersensitivity (allergic reactions),
- thirst, lacrimation disorder,
- chills,
- a ringing or buzzing sound in the ears (tinnitus),
- drug tolerance (i.e. an increase in dose becomes necessary to achieve the desired effect).

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

- Lymph node disease (lymphadenopathy),
- seizures, in particular in patients suffering from epilepsy or with a tendency to seizures, muscle spasms (involuntary contraction of the muscle),
- lowering of blood pressure, rarely accompanied by symptoms such as pounding or racing heartbeat,
- gum bleeding; increased appetite; tarry stool; tooth staining and damage,
- herpes simplex (disorder of the skin and mucosa), hives (urticaria),
- changes in body weight (loss or rise); cellulitis.

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

- Anaphylactic reaction,
- aggression,
- increased sensibility to pain (hyperalgesia),
- dental caries,
- biliary stasis, biliary colic,
- absence of menstrual bleeding (amenorrhoea),
- dependence and addiction (see section “How do I know if I am addicted?”).

Long term use of Ixyldone during pregnancy may cause life threatening withdrawal symptoms in the new-born. Symptoms to look for in the baby include irritability, hyperactivity and abnormal sleep pattern, high pitched cry, shaking, being sick, diarrhoea and not putting on weight.

Drug Withdrawal

When you stop taking Ixyldone, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst taking Ixyldone, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber,
- You feel you need to use more than the recommended dose,
- You are using the medicine for reasons other than prescribed,
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again.

If you notice any of these signs, it is important you talk to your prescriber.

Counteractive measures

If you observe any of the above listed side effects your doctor usually will take appropriate measures. The side effect constipation may be prevented by fiber enriched diet and increased drinking.

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.

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-releasetablets 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.

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