Package leaflet: Information for the patient

Oximel 5 mg prolonged-release tablets
Oximel 10 mg prolonged-release tablets
Oximel 15 mg prolonged-release tablets
Oximel 20 mg prolonged-release tablets
Oximel 30 mg prolonged-release tablets
Oximel 40 mg prolonged-release tablets
Oximel 60 mg prolonged-release tablets
Oximel 80 mg prolonged-release tablets

Oxycodone hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Oximel is and what it is used for

Oximel (active substance: oxycodone hydrochloride) is a centrally acting, strong painkiller from the group of opioids.
Oximel is used to treat severe pain, which can be adequately managed only with oipoid analgesics.
Oximel is indicated in adults and adolescents aged 12 years and older.

2. What you need to know before you take Oximel

Do not take Oximel
- 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 Oximel
- if you are older or debilitated,
- if your lung, liver or kidney function is severely impaired,
- if you suffer from myxoedema (certain illnesses of the thyroid gland), impaired function of the thyroid gland,
- if you suffer from adrenal insufficiency (Addison's disease),
- if you suffer from enlargement of the prostate (prostatic hypertrophy),
- if you suffer from alcoholism or are undergoing alcohol withdrawal

- if you suffer from known opioid-dependence,
- if you suffer from 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
Oximel has a primary dependence potential. When used for a long time tolerance to the effects and progressively higher doses may be required to maintain pain control.

Chronic use of Oximel may lead to physical dependence and a withdrawal syndrome may occur upon abrupt cessation. When a patient no longer requires therapy with oxycodone hydrochloride, it may advisable to taper the dose gradually to prevent symptoms of withdrawal.

When used as directed in patients suffering from chronic pain the risk of developing physical or psychological dependence is markedly reduced and needs to be weighed against the potential benefit. Please discuss this with your doctor.

Oximel 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.

This medicine should be avoided in patients with a history of or present alcohol and drug abuse.

Anti-doping warning
Athletes should be aware that this medicine may cause a positive reaction to "anti-doping tests". Use of Oximel 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 Oximel

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.

Oximel with food, drink and alcohol
Drinking alcohol whilst taking Oximel 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 Oximel.
You should avoid drinking grapefruit juice during your treatment with Oximel

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
Oximel should not be taken in pregnancy unless clearly necessary. There are only limited data from the use of oxycodone in pregnant women.
Oxycodone crosses the placenta into the blood circulation of the baby.

Prolonged use of oxycodone during pregnancy can cause withdrawal symptoms in newborns. Use of oxycodone during delivery can cause respiratory depression in the newborn.

Breast-feeding
You should not take Oximel when you are breast-feeding as oxycodone passes into breast milk.

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

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.

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

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.

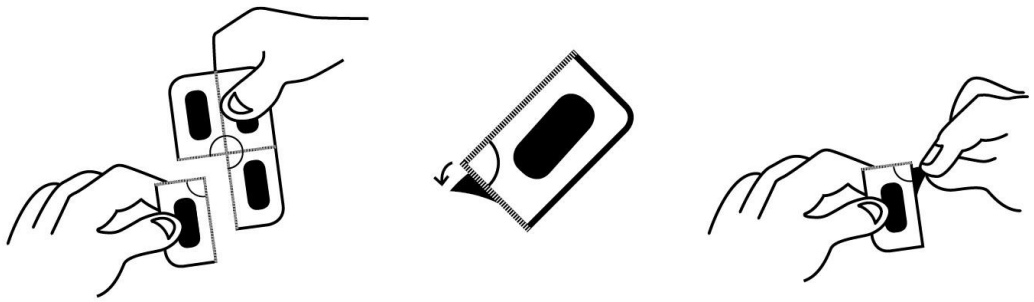
Use in children and adolescents
Oximel is not recommended in children younger than 12 years of age.

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.).

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 Oximel than you should"). The prolonged-release tablets may be taken with or independent of meals with a sufficient amount of liquid.

Oximel 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 Oximel according to a fixed schedule need rapidly acting painkillers as rescue medication to control breakthrough pain. Oximel 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 Oximel than you should
If you have taken more Oximel 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 Oximel
If you use a smaller dose of Oximel 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 Oximel more than once every 8 hours.

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

If you stop taking Oximel
Do not stop treatment without informing your doctor.
When a patient no longer requires therapy with Oximel, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal.

If you have any further questions on the use of this 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 Oximel 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)

Opioid withdrawal syndrome
As oxycodone hydrochloride has the potential to cause a drug addiction, there is a possibility to develop an opioid abstinence or withdrawal syndrome is characterized by some or all of the following: restlessness, watery eyes (lacrimation), rhinorrhoea, yawning, perspiration, chills, muscle pain, dilation of the pupil and irregular heartbeat (palpitations). Other symptoms also may develop including: irritability, anxiety, backache, joint pain, weakness, abdominal cramps, insomnia, nausea, anorexia, vomiting, diarrhea, or increased blood pressure, respiratory rate or heart rate.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Oximel

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.

[Oximel 5 mg]
Do not store above 25°C.

[Oximel 10 mg]
Do not store above 30°C.

[Oximel 15 mg / 20 mg / 30 mg / 40 mg / 60 mg / 80 mg]
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 Oximel contains

The active substance is oxycodone hydrochloride.

[5 mg]:
Each prolonged-release tablet contains 5 mg oxycodone hydrochloride corresponding to 4.5 mg oxycodone.
The other ingredients are:
Tablet core: Lactose monohydrate, ammonio methacrylate copolymer Type B, povidone (K29/32), talc, triacetin, stearyl alcohol, magnesium stearate.
Tablet coating: Hypromellose, talc, macrogol 400, titanium dioxide (E171), brilliant blue FCF (E133).

[10 mg]:
Each prolonged-release tablet contains 10 mg oxycodone hydrochloride corresponding to 9 mg oxycodone
The other ingredients are:
Tablet core:
Lactose monohydrate, Ammonio Methacrylate Copolymer, Type B, Povidone (K29/32), Talc, Triacetin, Stearyl alcohol, Magnesium stearate,
Tablet coating: Hypromellose, Talc, Macrogol 400, Titanium dioxide (E171)

[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, 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, 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, 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, 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, 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, Povidone (K29/32), Talc, Triacetin, Stearyl alcohol, Magnesium stearate
Tablet coating:
Hypromellose, Talc, Macrogol 400, Titanium dioxide (E171), Indigo carmine (E132), Iron oxide yellow (E172)

What Oximel looks like and contents of the pack
[Oximel 5 mg prolonged-release tablets]
Light blue, round, biconvex, prolonged-release tablets with a diameter of 6.9 – 7.3 mm and a height of 3.5 – 4.2 mm.

[Oximel 10 mg prolonged-release tablets]
White, round, biconvex, prolonged-release tablets with a diameter of 6.9 – 7.3 mm and a height of 3.5 – 4.2 mm.

[Oximel 15 mg prolonged-release tablets]
Grey, round, biconvex, prolonged-release tablets with a diameter of 6.9 – 7.3 mm and a height of 3.5 – 4.2 mm.

[Oximel 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 3.5 – 4.2 mm.

[Oximel 30 mg prolonged-release tablets]
Brown, round, biconvex, prolonged-release tablets with a diameter of 6.9 – 7.3 mm and a height of 3.5 – 4.2 mm.

[Oximel 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 3.5 – 4.2 mm.

[Oximel 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 5.0 – 5.6 mm.

[Oximel 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.

Oximel is available in child-resistant perforated unit dose blisters with 10x1, 14x1, 20x1, 25x1, 28x1, 30x1, 40x1, 50x1, 56x1, 60x1, 98x1 and 100x1 prolonged-release tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer
STADA Arzneimittel AG, Stadastrasse 2-18, D-61118 Bad Vilbel, Germany
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:
DE: Oxycodon-HCI AL 5 mg, 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg Retardtabletten
IE: Oximel 5, 10, 15, 20, 30, 40, 60, 80 mg prolonged release tablets
SK: Oxykodon Stada

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