30 mm

6 mm

10mm

Package leaflet: Information for the user

Alivio™ 5 mg prolonged-release tablets
Alivio™ 10 mg prolonged-release tablets
Alivio™ 20 mg prolonged-release tablets
Alivio™ 30 mg prolonged-release tablets
Alivio™ 40 mg prolonged-release tablets
Alivio™ 60 mg prolonged-release tablets
Alivio™ 80 mg prolonged-release tablets
Oxycodone hydrochloride

This medicine contains oxycodone 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Alivio™ is and what it is used for

This medicine has been prescribed for you to treat severe pain in adults and adolescents aged 12 years and older, which can be adequately managed only with opioid analgesics.
It contains the oxycodone 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.

2. What you need to know before you take Alivio™

Do not take Alivio™ if you:
- are allergic (hypersensitive) to oxycodone, or any of the other ingredients of the tablets (listed in section 6);
- have breathing problems, such as severe chronic obstructive lung disease, severe bronchial asthma or severe respiratory depression. Your doctor will have told you if you have any of these conditions. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected;
- have a condition where the small bowel does not work properly (paralytic ileus), your stomach empties more slowly than it should (delayed gastric emptying) or you have severe pain in your abdomen;
- have a heart problem after long-term lung disease (Cor pulmonale);
- have moderate to severe liver problems. If you have other long-term liver problems you should only take these tablets if recommended by your doctor;
- have ongoing problems with constipation;
- have increased carbon dioxide levels in the blood. Symptoms may include dizziness, drowsiness, fatigue, shortness of breath and headache;

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Alivio™ if you:
- are elderly or weakened
- if your lung, liver or kidney function is severely impaired (see also section 3 "Risk patients")
- have myxoedema (a thyroid disorder associated with dryness, coldness and swelling or puffiness of the skin affecting the face and limbs);
- have an under-active thyroid gland (hypothyroidism), as you may need a lower dose;
- or anyone in your family are or have ever been addicted to opioids, alcohol, prescription medicines or illegal drugs;
- feel very lightheaded or faint;
- have poor adrenal gland function (your adrenal gland is not working properly which may cause symptoms including weakness, weight loss, dizziness, feeling or being sick), for example due to Addison's disease;
- have a mental disorder as a result of an infection (toxic psychosis);
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more tablets 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.
- have an enlarged prostate gland, which causes difficulty in passing urine (in men);
- if you suffer from alcoholism or are undergoing alcohol withdrawal
- have inflammation of the pancreas (which causes severe pain in the abdomen and back);
- have problems with your gall bladder or bile duct;
- have inflammatory bowel disorders
- have low blood pressure (hypotension)
- have decreased blood volume (hypovolaemia); this can happen with severe external or internal bleeding, severe burns, excessive sweating, severe diarrhoea or vomiting;
- know you are suffering from a brain injury or tumour, or you have a head injury, severe headache or feel sick as this may indicate that the pressure in your skull is increased;
- have severely impaired lung function. Symptoms may include breathlessness and coughing;
- have a condition where your breathing stops for short periods whilst you are asleep, known as sleep apnoea;
- if you take MAO inhibitors (for the treatment of depression).

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

You may experience hormonal changes while taking these tablets. Your doctor may want to monitor these changes.

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 ***Alivio™*** tablets can also 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.
If you have concerns that you may become dependent on ***Alivio™*** tablets, it is important that you consult your doctor. Your doctor should have explained how long you will be using it for and when it is appropriate to stop, how to do this safely.
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.
Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your doctor about your treatment.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent or addicted on Alivio™ 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 Alivio™ 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')

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.

Withdrawal
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. 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 Alivio™).
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.

Do not inject **Alivio™** tablets. This can cause serious side effects including tissue death at the site of injection, infection, inflammation of the lungs and damage to the heart which may be fatal.

Long term treatment and abuse
Alivio™ has primary dependence potential. When used for a long time tolerance to the effects may develop and progressively higher doses may be required to maintain pain control.

Chronic use of Alivio™ may lead to physical dependence and a withdrawal syndrome may occur upon abrupt cessation of therapy. When a patient no longer requires therapy with oxycodone hydrochloride, it may be 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. Alivio™ is for oral use only.

Sleep-related breathing disorders
Alivio™ 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.

Children under 12 years of age
Alivio™ should not be used in children under 12 years of age because of safety and efficacy concerns.

Elderly patients
In elderly patients without impairment of kidney and/or liver function a dose adjustment is usually not necessary.

Other medicines and Alivio™

Taking Alivio™ tablets at the same time as other medicines that slow down the central nervous system can cause slow or difficulty breathing (respiratory depression), severe sleepiness, loss of consciousness and death. These medicines include:
- other medicines used to treat pain known as opioids (such as codeine or morphine);
- medicines used to treat epilepsy (gabapentinoids) such as pregabalin;
- medicines used to treat anxiety;
- medicines used to make you feel sleepy (such as benzodiazepines);
- medicines used to treat psychiatric or mental disorders (such as phenothiazines);
- anaesthetics;
- muscle relaxants;
- medicines used to treat high blood pressure;
- a type of medicine used to treat depression known as monoamine oxidase inhibitors (MAOIs), such as tranylcypromine, phenelzine and isocarboxazid.

You should not take Alivio™ tablets if you are currently taking this type of medicine, or have taken this medicine in the last two weeks.

Because of this, your doctor will only prescribe Alivio™ tablets where there are no other treatment options, and only in small doses for short periods of time. If you or your friends, family or caregivers notice that you are having difficulty breathing or that you have become very sleepy or lost consciousness you (or they) should inform your doctor **immediately**.

Taking Alivio™ tablets with medicines used to treat depression known as Selective Serotonin Re-uptake Inhibitors (SSRIs) or Serotonin Norepinephrine Re-uptake Inhibitors (SNRIs) can cause a condition known as serotonin toxicity. The symptoms of this include agitation, seeing or hearing things that aren't real (hallucinations), loss of consciousness, a fast heartbeat, blood pressure changes, increased body temperature, muscle twitching, lack of coordination, stiffness, feeling or being sick, or diarrhoea. If you are taking SSRI or SNRI medicines such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline or venlafaxine your doctor may reduce your dose of Alivio™ tablets.

Please tell your doctor or pharmacist if you are taking have recently taken or might take 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.

Tell your doctor or pharmacist if you are taking
- a type of medicine used to treat depression known as tricyclic antidepressants, such as amitriptyline, clomipramine, imipramine, lofepramine or nortriptyline;
- medicines used to treat allergies, such as cetirizine, fexofenadine or chlorphenamine;
- quinidine (a medicine to treat a fast heart beat);
- cimetidine (a medicine for stomach ulcers, indigestion or heartburn);
- antifungal medicines (such as ketoconazole, voriconazole, itraconazole and posaconazole);
- antibiotics (such as clarithromycin, erythromycin or telithromycin);
- medicines known as 'protease inhibitors' to treat HIV (e.g. boceprevir, ritonavir, indinavir, nelfinavir or saquinavir);
- rifampicin (to treat tuberculosis);
- medicines used to treat seizures, fits or convulsions such as carbamazepine and phenytoin
- a herbal remedy used to treat depression known as St. John's Wort (also known as Hypericum perforatum);
- antihistamines;
- medicines to treat Parkinson's disease.

Do not use Alivio™ for acute post-operative pain because of the increased risk of dependency and developing serious breathing problems.

Alivio™ with food, drink and alcohol
Drinking alcohol whilst taking Alivio™ 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 Alivio™.
You should avoid drinking grapefruit juice during your treatment with this medicine.

Pregnancy, breast-feeding and fertility
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
Do not take Alivio™ if you are pregnant or think you might be pregnant unless you have discussed this with your doctor and the benefits of treatment are considered to outweigh the potential harm to the baby. If you take Alivio™ 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 this medicine while you are breastfeeding as oxycodone 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 or dizziness 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.

This 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.

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

Information on sodium content
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. How to take Alivio™

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 Alivio™, 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 Alivio™).

For doses not realisable/practicable with this medicinal product other strengths and medicinal products are available.

Your prescriber should have discussed with you, how long the course of this medicine 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 (aged 12 years and older)
The usual initial dose is 10 mg of oxycodone hydrochloride in 12 hourly intervals. Some patients may benefit from a starting dose of 5 mg to minimise the incidence of adverse reactions.

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. Patients who have already taken opioids can start treatment with higher dosages taking into account their experience with opioid treatment.
Some patients who receive Alivio™ according to a fixed schedule need rapidly acting painkillers as rescue medication to control breakthrough pain. Alivio™ is not intended for the treatment of breakthrough pain.
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.
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.

xxxxxx

10mm

SAME SIZE ARTWORK
560 x 285 mm

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.

Route and method of administration
Oral use. It is not recommended to take Alivio™ with alcoholic beverages.

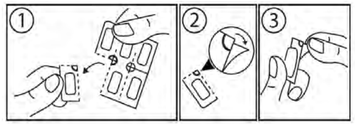
Swallow the prolonged-release tablets with a sufficient amount of liquid (½ glass of water) with or without food in the morning and in the evening following a fixed schedule (e.g. at 8 a.m. and 8 p.m.).

Alivio™ 5 mg prolonged-release tablets
Alivio™ must not be taken divided, broken, chewed or crushed as this leads to rapid oxycodone release due to the damage of the prolonged-release properties. The administration of divided, broken, chewed or crushed Alivio™ leads to a rapid release and absorption of a potentially fatal dose of oxycodone (see section "If you take more Alivio™ than you should")

Alivio™ 10 mg prolonged-release tablets
Alivio™ 20 mg prolonged-release tablets
Alivio™ 30 mg prolonged-release tablets
Alivio™ 40 mg prolonged-release tablets
Alivio™ 60 mg prolonged-release tablets
Alivio™ 80 mg prolonged-release tablets

The prolonged-release tablet can be divided into equal doses.
Alivio™ must not be chewed or crushed as this leads to rapid oxycodone release due to the damage of the prolonged-release properties. The administration of chewed or crushed Alivio™ leads to a rapid release and absorption of a potentially fatal dose of oxycodone (see section "If you take more Alivio™ than you should").

Opening instruction for the blister
This medicinal product is packed in a perforated unit dose blister. You cannot press out the prolonged-release tablets through the blister. Please observe the following opening instruction for the blister:



1. Tear off a single dose along the perforation line of the blister.
2. Hereby an unsealed area is accessible which is located at the position, where the perforation lines have crossed.
3. Pull at the unsealed "strap" to peel off the cover seal.

Your doctor will adjust the dosage depending on the pain intensity and how you respond to the treatment. Take the number of prolonged-release tablets determined by your doctor twice daily.

If you take more Alivio™ than you should
If you have taken more Alivio™ as prescribed you should inform your doctor or your local poison control centre immediately. The following symptoms may occur: constricted pupils (miosis), depressed breathing (respiratory depression), skeletal muscle flaccidity and drop in blood pressure. In severe cases circulatory collapse, mental and motor inactivity (torpor), 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, a brain disorder (known as toxic leukoencephalopathy). In no case you should expose yourself to situations requiring elevated concentration e.g. driving a car.

If you forget to take Alivio™
If you use a smaller dose of Alivio™ than directed or you miss the intake of Alivio™, 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 your recommended dose as directed.
You should also take Alivio™ if the time to the regular next intake is shorter, but postpone the next intake by 8 hours. In principle, you should not take Alivio™ more than once every 8 hours.
Do not take a double dose to make up for a forgotten dose.

If you stop taking Alivio™
Do not stop treatment without informing your doctor.
When a patient no longer requires therapy with Alivio™, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal.
A withdrawal syndrome may occur upon abrupt cessation of therapy. For symptoms of the withdrawal syndrome see section 4.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, these medicine can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are rare. Tell your doctor immediately if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body. These may be signs of a serious allergic reaction.

The most serious side effect is a condition where you breathe more slowly or weakly than usual (respiratory depression) and can lead to severe sleepiness and loss of consciousness. This side effect may affect up to 1 in 100 people and is more likely to occur when taking certain other medicines (see section 2 'Other medicines and **Alivio™** tablets'). **Tell your doctor immediately** if this happens to you. You may wish to ask your friends, family or caregivers to monitor you for these signs and symptoms.

Other possible side effects
Very common (may affect more than 1 in 10 people)
- Constipation (your doctor can prescribe a laxative to overcome this problem);
- Feeling or being sick (this should normally wear off after a few days, however your doctor can prescribe an anti-sickness medicine if it continues to be a problem);
- Drowsiness (this is most likely when you start taking your tablets or when your dose is increased, but it should wear off after a few days);
- Dizziness;
- Headache;
- Itchy skin.

Common (may affect up to 1 in 10 people)
- Dry mouth, decreased appetite, indigestion, abdominal pain or discomfort, diarrhoea.
- Confusion, depression, a feeling of unusual weakness, shaking, lack of energy, tiredness, anxiety, nervousness, difficulty in sleeping, abnormal thoughts or dreams.
- Difficulty in breathing or wheezing, shortness of breath, decreased cough reflex.
- Rash.
- Sweating.

Uncommon (May affect up to 1 in 100 people)
- a need to take higher doses to gain the same level of pain relief (tolerance);
- withdrawal symptoms (see section 'Drug withdrawal');
- Difficulty in swallowing, belching, hiccups, wind, a condition where the bowel does not work properly (ileus), inflammation of the stomach, changes in taste or unpleasant taste;
- A feeling of dizziness or spinning (vertigo), hallucinations, mood changes, unpleasant or uncomfortable mood, a feeling of extreme happiness , disorientation, restlessness, agitation, generally feeling unwell, loss of memory, difficulty in speaking, reduced sensitivity to pain or touch, tingling or numbness, seizures, fits or convulsions blurred vision, fainting, unusual muscle stiffness or slackness, involuntary muscle contractions or spasms;
- Difficulty or pain in passing urine, impotence, decreased sexual drive, low levels of sex hormones in the blood ('hypogonadism', seen in a blood test).
- Fast, irregular heart beat, low blood pressure, palpitations, a feeling of lightheadedness, dizziness or fainting, flushing of the skin.
- Dehydration, thirst, chills, swelling of the hands, ankles or feet.
- Dry skin, severe flaking or peeling of the skin
- Redness of the face, reduction in size of the pupils in the eye, high temperature.
- A need to take increasingly higher doses of the tablets to obtain the same level of pain relief (tolerance).
- Colicky abdominal pain or discomfort.
- A worsening of liver function tests (seen in a blood test).
- hypotonia

Rare (may affect up to 1 in 1,000 people)
- Low blood pressure or feeling faint, especially on standing up;
- A raised, itchy rash (hives).

Frequency not known (cannot be estimated from the available data)
- Dependence and addiction (see 'How do I know if I am addicted?' in section 2 of the leaflet);
- Withdrawal symptoms (see 'Drug withdrawal' in section 2 of the leaflet);
- A need to take increasingly higher doses of the tablets to obtain the same level of pain relief (tolerance);
- An increased sensitivity to pain.
- Aggression.
- Tooth decay.
- Absence of menstrual periods.
- A blockage in the flow of bile from the liver (cholestasis). This can cause itchy skin, yellow skin, very dark urine and very pale stools.
- 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)

Long term use of **Alivio™** during pregnancy may cause life-threatening withdrawal symptoms in the newborn. 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.
You may see the remains of the tablets in your faeces. This should not affect how the tablets work.

Drug Withdrawal
When you stop taking this medicine, 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 this medicine, 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 fibre enriched diet and increased drinking. If you are suffering from sickness or vomiting your doctor will prescribe you an appropriate medicine.

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 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 Alivio™

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 or label, 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. Contents of the pack and other information

What Alivio™ contains
- The active substance is oxycodone hydrochloride.

Alivio™ 5 mg prolonged-release tablets:
Each prolonged-release tablet contains 5 mg oxycodone hydrochloride as active substance, equivalent to 4.5 mg oxycodone.
- The other ingredients are:

Tablet core: Sugar spheres (sucrose, maize starch), Hypromellose, Talc, Hydrochloric acid (HCl for pH adjustment), Ethyl cellulose, Hydroxypropylcellulose, Propylene glycol, Carmellose sodium, Cellulose microcrystalline, Magnesium stearate (Ph. Eur.), Silica colloidal anhydrous
Tablet coating:
Polyvinyl alcohol, Titanium dioxide (E171), Macrogol 3350, Talc

Alivio™ 10 mg prolonged-release tablets:
Each prolonged-release tablet contains 10 mg oxycodone hydrochloride as active substance, equivalent to 9 mg oxycodone.
- The other ingredients are:

Tablet core: Sugar spheres (sucrose, maize starch), Hypromellose, Talc, Hydrochloric acid (HCl for pH adjustment), Ethyl cellulose, Hydroxypropyl cellulose, Propylene glycol, Carmellose sodium, Cellulose microcrystalline, Magnesium stearate (Ph. Eur.), Silica colloidal anhydrous
Tablet coating: Polyvinyl alcohol, Titanium dioxide (E171), Macrogol 3350, Iron oxide red (E172), Talc

Alivio™ 20 mg prolonged-release tablets:
Each prolonged-release tablet contains 20 mg oxycodone hydrochloride as active substance, equivalent to 17.9 mg oxycodone.
- The other ingredients are:

Tablet core: Sugar spheres (sucrose, maize starch), Hypromellose, Talc, Hydrochloric acid (HCl for pH adjustment), Ethyl cellulose, Hydroxypropylcellulose, Propylene glycol, Carmellose sodium, Cellulose microcrystalline, Magnesium stearate (Ph. Eur.), Silica colloidal anhydrous
Tablet coating: Polyvinyl alcohol, Titanium dioxide (E171), Macrogol 3350, Talc

Alivio™ 30 mg prolonged-release tablets:
Each prolonged-release tablet contains 30 mg oxycodone hydrochloride as active substance, equivalent to 26.9 mg oxycodone.
- The other ingredients are:

Tablet core: Sugar spheres (sucrose, maize starch), Hypromellose, Talc, Hydrochloric acid (HCl for pH adjustment), Ethyl cellulose, Hydroxypropylcellulose, Propylene glycol, Carmellose sodium, Cellulose microcrystalline, Magnesium stearate (Ph. Eur.), Silica colloidal anhydrous

Tablet coating: Polyvinyl alcohol, Titanium dioxide (E171), Iron oxide yellow (E172), Macrogol 3350, Talc

Alivio™ 40 mg prolonged-release tablets:
Each prolonged-release tablet contains 40 mg oxycodone hydrochloride as active substance, equivalent to 36 mg oxycodone.
- The other ingredients are:

Tablet core: Sugar spheres (sucrose, maize starch), Hypromellose, Talc, Hydrochloric acid (HCl for pH adjustment), Ethyl cellulose, Hydroxypropylcellulose, Propylene glycol, Carmellose sodium, Cellulose microcrystalline, Magnesium stearate (Ph. Eur.), Silica colloidal anhydrous
Tablet coating: Polyvinyl alcohol, Titanium dioxide (E171), Iron oxide red (E172), Macrogol 3350, Talc

Alivio™ 60 mg prolonged-release tablets:
Each prolonged-release tablet contains 60 mg oxycodone hydrochloride as active substance, equivalent to 53.8 mg oxycodone.
- The other ingredients are:

Tablet core: Sugar spheres (sucrose, maize starch), Hypromellose, Hydrochloric acid (HCl for pH adjustment), Talc, Ethyl cellulose, Hydroxypropylcellulose, Propylene glycol, Carmellose sodium, Cellulose microcrystalline, Magnesium stearate (Ph. Eur.), Silica colloidal anhydrous
Tablet coating: Polyvinyl alcohol, Macrogol 3350, Iron oxide yellow (E172), Talc

Alivio™ 80 mg prolonged-release tablets:
Each prolonged-release tablet contains 80 mg oxycodone hydrochloride as active substance, equivalent to 72 mg oxycodone.
- The other ingredients are:

Tablet core: Sugar spheres (sucrose, maize starch), Hypromellose, Hydrochloric acid (HCl for pH adjustment), Talc, Ethyl cellulose, Hydroxypropylcellulose, Propylene glycol, Carmellose sodium, Cellulose microcrystalline, Magnesium stearate (Ph. Eur.), Silica colloidal anhydrous
Tablet coating: Polyvinyl alcohol, Iron oxide red (E172), Macrogol 3350, Talc

What Alivio™ looks like and contents of the pack

Alivio™ 5 mg prolonged-release tablets
White to off-white, round, biconvex, film coated tablets. The height of the tablet is between 3.3 and 4.3 mm, the diameter is 5.2 mm.

Alivio™ 10 mg prolonged-release tablets
Pink, oblong, biconvex, film coated tablets with break scores on both sides. The height of the tablet is between 4 and 5 mm, the width is 4.8 mm and the length is 10.3 mm.
The tablet can be divided into equal doses.
Alivio™ 20 mg prolonged-release tablets
White to off-white, oblong, biconvex, film coated tablets with break scores on both sides. The height of the tablet is between 3.3 and 4.3 mm, the width is 4.8 mm and the length is 10.3 mm.
The tablet can be divided into equal doses.

Alivio™ 30 mg prolonged-release tablets
Yellow, oblong, biconvex, film coated tablets with break scores on both sides. The height of the tablet is between 3.8 and 4.8 mm, the width is 5.3 mm and the length is 11.3 mm.
The tablet can be divided into equal doses.

Alivio™ 40 mg prolonged-release tablets
Pink, oblong, biconvex, film coated tablets with break scores on both sides. The height of the tablet is between 4.8 and 5.8 mm, the width is 5.8 mm and the length is 12.4 mm.
The tablet can be divided into equal doses.

Alivio™ 60 mg prolonged-release tablets
Dark yellow, oblong, biconvex, film coated tablets with break scores on both sides. The height of the tablet is between 5 and 6 mm, the width is 6.8 mm and the length is 14.5 mm.
The tablet can be divided into equal doses.

Alivio™ 80 mg prolonged-release tablets
Red, oblong, biconvex, film coated tablets with break scores on both sides. The height of the tablet is between 5.8 and 6.8 mm, the width is 7.4 mm and the length is 15.5 mm.
The tablet can be divided into equal doses.
Pack sizes:
10x1, 14x1, 20x1, 28x1, 30x1, 50x1, 56x1, 98x1, 100x1 prolonged-release tablets in white opaque perforated unit dose blister.
10, 20, 30, 50, 100 prolonged-release tablets in bottles with closure.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
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Manufacturer
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Alivio™ 5mg prolonged-release tablets; PL 17907/0558
Alivio™ 10mg prolonged-release tablets; PL 17907/0559
Alivio™ 20mg prolonged-release tablets; PL 17907/0560
Alivio™ 30mg prolonged-release tablets; PL 17907/0561
Alivio™ 40mg prolonged-release tablets; PL 17907/0562
Alivio™ 60mg prolonged-release tablets; PL 17907/0563
Alivio™ 80mg prolonged-release tablets; PL 17907/0564

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V21 11-02-25 D0

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SAME SIZE ARTWORK
560 x 285 mm