PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Oxyargin 5 mg/2.5 mg prolonged-release tablets
Oxyargin 10 mg/5 mg prolonged-release tablets
Oxyargin 20 mg/10 mg prolonged-release tablets
Oxyargin 30 mg/15 mg prolonged-release tablets
Oxyargin 40 mg/20 mg prolonged-release tablets

oxycodone hydrochloride/naloxone hydrochloride

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

What is in this leaflet

1. What Oxyargin is and what it is used for

You have been prescribed Oxyargin for the treatment of severe pain, which can be adequately managed only with opioid analgesics.

How Oxyargin relieves pain
Oxyargin contains oxycodone hydrochloride and naloxone hydrochloride as active substances. Oxycodone hydrochloride is responsible for the pain-killing effect of Oxyargin and is a potent analgesic (“painkiller”) of the opioid group.

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

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

2. What you need to know before you take Oxyargin

Do not take Oxyargin
- if you are allergic to oxycodone hydrochloride, naloxone hydrochloride or any of the other ingredients of this medicine (listed in section 6),
- if your breathing is not able to supply enough oxygen to the blood, and get rid of carbon dioxide produced in the body (respiratory depression),
- if you suffer from a severe chronic lung disease associated with narrowing of the airways (chronic obstructive pulmonary disease or COPD),
- if you suffer from a condition known as cor pulmonale. In this condition the right side of the heart becomes enlarged, due to increased pressure inside blood vessels in the lung etc. (e.g. as a result of COPD – see above),

- if you suffer from severe bronchial asthma,
- if you have paralytic ileus (a type of bowel obstruction) not caused by opioids,
- if you have moderate to severe liver dysfunction.

Warnings and precautions
Talk to your doctor or pharmacist before taking Oxyargin
- if you are elderly or debilitated (weak),
- if you have paralytic ileus (a type of bowel obstruction) caused by opioids,
- if you have kidney problems,
- if you have mild liver problems,
- if you have severe lung problems (i.e. reduced breathing capacity),
- if you suffer from an problems that is accompanied by common respiratory interruptions and makes you feel sleepy during the day (sleep apnoea),
- if you have myxoedema (a thyroid disorder, with dryness, coldness and swelling [‘puffiness’] of the skin, affecting the face and limbs),
- if your thyroid gland is not producing enough hormones (underactive thyroid, or hypothyroidism),
- have poor adrenal gland function (your adrenal gland is not working properly) for example Addison’s disease,
- if you have a mental illness accompanied by a (partial) loss of reality (psychosis), due to alcohol or intoxication with other substances (substance-induced psychosis),
- if you suffer from gallstone problems,
- if your prostate gland is abnormally enlarged (prostate hypertrophy),
- if you suffer from *alcoholism* or delirium tremens,
- if your pancreas is inflamed (pancreatitis),
- if you have low blood pressure (hypotension),
- if you have high blood pressure (hypertension),
- if you have pre-existing cardiovascular disease,
- if you have a head injury (due to the risk of increased brain pressure),
- if you suffer from epilepsy or are prone to seizures,
- if you are also taking MAO inhibitors (used to treat depression or Parkinson’s disease), e.g. medicines containing tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid
- if you feel sleepy or if you fall asleep sometimes,
- 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.

Tell your doctor if any of the above has ever applied to you in the past. Also, please tell your doctor if you develop any of the above disorders while you are taking Oxyargin.

Repeated use of Oxyargin may lead to dependence and abuse which may result in life-threatening overdose. If you have concern that you may become dependent on Oxyargin, it is important that you consult your doctor.

Sleep-related breathing disorders
Oxyargin 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.

The most serious result of opioid overdose is **respiratory depression** (slow and shallow breathing). This may also cause blood oxygen levels to fall, resulting in possible fainting, etc.

There is no clinical experience with Oxyargin in patients with cancer associated to peritoneal metastases or with beginning bowel obstruction in advanced stages of digestive and pelvic cancers. Therefore, the use of Oxyargin in these patients is not recommended.

Children and adolescents
The safety and benefits of Oxyargin in children and adolescents below 18 years has not been established.

How to use Oxyargin correctly

Diarrhoea
If you experience severe diarrhoea at the start of treatment, this may be due to the effect of naloxone. It may be a sign that bowel function is returning to normal. Such diarrhoea can occur within the first 3-5 days of treatment. If diarrhoea should persist after 3-5 days, or give you cause for concern, please contact your doctor.

Switching to Oxyargin
If you have been using high doses of another opioid, withdrawal symptoms may occur when you initially switch to Oxyargin treatment, e.g. restlessness, bouts of sweating and muscle pain. If you experience such symptoms, you may need to be specially monitored by your doctor. Oxyargin is not suitable for withdrawal treatment.

Surgery
If you need to undergo surgery, please tell your doctors that you are taking Oxyargin.

Long-term treatment
If used over the long term, you may become tolerant to Oxyargin. This means you may need a higher dose to achieve the desired pain relief. Also, long-term use of Oxyargin may lead to physical dependence. Withdrawal symptoms may occur if treatment is stopped too suddenly (restlessness, bouts of sweating, muscle pain). If you no longer need treatment, you should reduce your daily dose gradually, in consultation with your doctor.

Psychological dependence
The active substance oxycodone hydrochloride alone has an abuse profile similar to other strong opioids (strong analgesics). There is potential for development of psychological dependence. Oxycodone hydrochloride containing products should be avoided in patients with a present or past abuse of alcohol, drugs or medicines.

Misuse
You should never misuse Oxyargin prolonged-release tablets by dissolving and injecting them (e.g. into a blood vessel). In particular, they contain talc, which can cause destruction of local tissue (necrosis) and changes in lung tissue (lung granuloma). Such abuse can also have other serious consequences and may even be fatal.

Incorrect use of Oxyargin
Oxyargin 5 mg / 2.5 mg
The tablet must be swallowed whole and not be divided, broken, chewed or crushed.

Oxyargin 10 mg / 5 mg
Please be aware that, even though, the tablets can be divided, they must not be broken, chewed or crushed.

Oxyargin 20 mg/10 mg, 30 mg/15 mg and 40 mg/20 mg
Please be aware that, even though, the tablets can be divided, they must not be broken, chewed or crushed.

Taking chewed or crushed tablets may affect the slow release properties of the tablet and lead to the absorption of a potentially lethal dose of oxycodone hydrochloride (see under “If you take more Oxyargin than you should”).

Abuse
Oxyargin should never be abused, particularly if you have a drug addiction. If you are addicted to substances such as heroin, morphine or methadone, severe withdrawal symptoms are likely if you abuse Oxyargin because it contains the ingredient naloxone. Pre-existing withdrawal symptoms may be made worse.

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

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

The risk of side effects is increased if you take Oxyargin at the same time as medicines which affect brain function. In this case, the side effects of Oxyargin may be enhanced and may be life threatening. For example, tiredness/drowsiness may occur, respiratory depression (slow, shallow breathing) may get worse or coma. Because of this, concomitant use should only be considered when other treatment options are not possible.

Examples of medicines which affect brain function include:
- other potent painkillers (opioids),
- medicines to treat epilepsy, pain, and anxiety such as gabapentin and pregabalin
- sleep medication and tranquilisers (sedatives e.g. benzodiazepines, hypnotics, anxiolytics),
- antidepressants,
- medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics),
- other medicines to treat psychiatric or mental disorders (antipsychotics e.g. phenothiazines and neuroleptics).

However, if your doctor does prescribe Oxyargin together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

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.

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.

Tell your doctor if you are taking one of the following medicinal products:
- medicines that decrease the blood's clotting ability (coumarin derivatives), this clotting time may be speeded up or slowed down,
- antibiotics of the macrolide type (such as clarithromycin),
- antifungal medicines of the azole type (e.g. ketoconazole),
- ritonavir or other protease inhibitors (used to treat HIV),
- cimetidine (used to treat stomach ulcers, indigestion or heartburn)
- rifampicin (used to treat tuberculosis),
- carbamazepine (used to treat seizures, fits or convulsions and certain pain conditions),
- phenytoin (used to treat seizures, fits or convulsions)
- St. John's Wort (a herbal remedy also known as *Hypericum perforatum*)
- quinidine (used to treat an irregular heartbeat).

No interactions are expected between Oxyargin and paracetamol, acetylsalicylic acid or naltrexone.

Oxyargin with food and drink and alcohol
Drinking alcohol whilst taking Oxyargin 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're taking Oxyargin.

You should avoid drinking grapefruit juice while you are taking Oxyargin.

Pregnancy and breast-feeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy
Use of Oxyargin should be avoided to the extent possible during pregnancy. If used over prolonged periods during pregnancy, oxycodone hydrochloride may lead to withdrawal symptoms in newborn infants. If oxycodone hydrochloride is given during childbirth, respiratory depression (slow and shallow breathing) may occur in the newborn infant.

Breast-feeding
Breast-feeding should be discontinued during treatment with Oxyargin. Oxycodone hydrochloride passes into breast milk. It is not known whether naloxone hydrochloride also passes into breast milk. Therefore, a risk for the suckling infant cannot be excluded in particular following intake of multiple doses of Oxyargin.

Driving and using machines
Oxyargin may affect your ability to drive or operate machines. In particular, this is likely at the start of Oxyargin therapy, after a dose increase or after switching from a different medication. However, these side effects disappear once you are on a stable Oxyargin dose.

Medicines containing oxycodone/naloxone such as Oxyargin have been associated with sleepiness and episodes of abruptly falling asleep. If you have this side effect, you must not drive or operate machinery. Talk to your doctor if these side effects occur.

Ask your doctor whether you may drive or operate machines.

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

3. How to take Oxyargin

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

Unless otherwise prescribed by your doctor, the usual dose is:

Adults
The usual starting dose is 10 mg oxycodone hydrochloride/5 mg naloxone hydrochloride as prolonged-release tablet(s) every 12 hours.

Your doctor will decide how much Oxyargin you should take every day and how to divide your total daily dose into morning and evening doses. Your doctor will also decide on any necessary dose adjustments during treatment. Your dose will be adjusted according to your level of pain and individual sensitivity. You should be given the lowest dose needed for pain relief. If you have already been treated with opioids, Oxyargin treatment can be started at a higher dose.

The maximum daily dose is 160 mg oxycodone hydrochloride and 80 mg naloxone hydrochloride. If you need a higher dose, your doctor may give you additional oxycodone hydrochloride without naloxone hydrochloride. However, the maximum daily dose of oxycodone hydrochloride should not exceed 400 mg.

The beneficial effect of naloxone hydrochloride on bowel activity may be affected if additional oxycodone hydrochloride is given without additional naloxone hydrochloride.

If you are switched from Oxyargin to another strong opioid pain medication you have to anticipate, that your bowel function will probably worsen.

If you experience pain between two doses of Oxyargin, you probably may need a rapid-acting painkiller. Oxyargin is not suitable for this. In this case, please talk to your doctor.

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

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

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

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

Use in children and adolescents below 18 years of age
Oxyargin has not yet been studied in children and adolescents under 18 years of age. Its safety and effectiveness have not been proven in children and adolescents. For this reason, Oxyargin use in children and adolescents under 18 years of age is not recommended.

Method of administration
For oral use.
Take Oxyargin every 12 hours, according to a fixed time schedule (e.g. at 8 o’clock in the morning and 8 o’clock in the evening).

Oxyargin 5 mg/2.5 mg
You should take Oxyargin with sufficient liquid (½ glass of water). The tablet must be swallowed whole and not divided, broken, chewed or crushed. The tablet may be taken with or without food.

Oxyargin 10 mg/5 mg, 20 mg/10 mg, 30 mg/15 mg and 40 mg/20 mg
You should take Oxyargin with sufficient liquid (½ glass of water). The tablet can be divided into equal doses. However, it must not be broken, chewed or crushed. The tablet may be taken with or without food.

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

If you take more Oxyargin than you should
If you have taken more than the prescribed dose of Oxyargin you must inform your doctor immediately.
An overdose may result in:
- narrowed pupils,
- slow and shallow breathing (respiratory depression),
- a narcotic-like state (drowsiness to the point of unconsciousness),
- low muscle tone (hypotonia),
- reduced pulse rate,
- a drop in blood pressure.

In severe cases, loss of consciousness (coma), fluid on the lungs and circulatory collapse may occur, which may be fatal in some cases.

You should avoid situations which require a high level of alertness, e.g. driving.

If you forget to take Oxyargin
If you forget to take Oxyargin or if you take a dose lower than the one prescribed, you may not feel any painkilling effect.
If you should forget to take your dose, please follow the instructions below:
- if your next usual dose is due in 8 hours' time or more: take the forgotten dose immediately and continue with your normal dosing schedule.
- if your next usual dose is due within less than 8 hours' time: take the forgotten dose. Then, wait another 8 hours before taking your next dose. Try to get back on track with your original dosing schedule (e.g. 8 o'clock in the morning and 8 o'clock in the evening). Do not take more than one dose within any 8-hour period.

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

If you stop taking Oxyargin
Do not stop your treatment with Oxyargin without consulting your doctor.

If you do not require any further treatment, you must reduce the daily dose gradually after talking to your doctor. In this way, you will avoid withdrawal symptoms, such as restlessness, bouts of sweating and muscle pain.

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

4. Possible side effects

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

Important side effects to look out for, and what to do if you are affected
If you are affected by any of the following important side effects, consult your nearest doctor immediately.

Slow and shallow breathing (respiratory depression) is the main danger of an opioid overdose. It mostly occurs in elderly and debilitated (weak) patients. Opioids can also cause a severe drop in blood pressure in susceptible patients.

Side effects are subdivided below into two sections; treatment of pain and treatment with the active substance oxycodone hydrochloride alone.

The following side effects were observed in patients with pain treatment

Common (may affect up to 1 in 10 people)
- decreased appetite up to loss of appetite
- difficulty in sleeping, tiredness or debility
- a feeling of dizziness or 'spinning', headache, drowsiness
- vertigo
- hot flushes
- abdominal pain, constipation, diarrhoea, dry mouth, indigestion, being sick, feeling sick, wind
- itchy skin, skin reactions, sweating
- general weakness

Uncommon (may affect up to 1 in 100 people)
- hypersensitivity/allergic reactions
- restlessness, abnormal thoughts, anxiety, confusion, depression, nervousness
- reduced sexual drive
- epileptic seizures (especially in persons with epileptic disorder or predisposition to seizures), difficulties to concentrate, speech disorder, fainting, shaking

- taste anomalies
- feeling sleepy or fatigued and sluggish (lethargy)
- vision impairment
- chest tightness especially if you already have coronary heart disease, palpitations
- drop in blood pressure, rise in blood pressure
- difficulties of breathing, runny nose, cough
- abdominal bloating
- hepatic enzymes increased, biliary colic
- muscle cramps, muscle twitches, muscle pain
- increased urge to urinate
- withdrawal symptoms such as agitation, chest pain, chills, generally feeling unwell, pain, swelling of hands, ankles or feet
- thirst
- weight loss
- injuries from accidents

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

Not known (frequency cannot be estimated from the available data)
- euphoric mood, hallucinations, nightmares, aggression
- pins and needles, severe drowsiness
- shallow breathing
- belching
- difficulties in passing urine
- erectile dysfunction
- sleep apnoea (breathing pauses during sleep)

The active substance oxycodone hydrochloride, if not combined with naloxone hydrochloride, is known to have the following differing side-effects

Oxycodone can cause breathing problems (respiratory depression), reduction in size of the pupil in the eye, cramping of the bronchial muscles and cramping of the smooth muscles, as well as depression of the cough reflex.

Common (may affect up to 1 in 10 people)
- altered mood and personality changes (e.g. depression, feeling of extreme happiness), decreased activity, increased activity
- hiccups
- difficulties in passing urine

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

Rare (may affect up to 1 in 1,000 people)
- Herpes simplex
- increased appetite
- black (tarry) stools, gingival bleeding
- itching rash (urticaria)

Not known (frequency cannot be estimated from the available data)
- acute generalised allergic reactions (anaphylactic reactions)
- increased sensitivity to pain
- tooth decay
- problems with bile flow
- absence of menstrual periods
- long term use of oxycodone 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

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 at: 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 Oxyargin

Keep this medicine out of the sight and reach of children.

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

Blister:
Do not store above 25°C.

Bottles:
Do not store above 30 °C.
Shelf life after first opening: 3 months.

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 Oxyargin contains

The active substances are oxycodone hydrochloride and naloxone hydrochloride.

Oxyargin 5 mg/2.5 mg
Each prolonged-release tablet contains 5 mg of oxycodone hydrochloride (equivalent to 4.5 mg oxycodone) and 2.5 mg of naloxone hydrochloride (as 2.73 mg naloxone hydrochloride dihydrate, equivalent to 2.25 mg naloxone).

Oxyargin 10 mg/5 mg
Each prolonged-release tablet contains 10 mg of oxycodone hydrochloride (equivalent to 9 mg oxycodone) and 5 mg of naloxone hydrochloride (as 5.45 mg naloxone hydrochloride dihydrate, equivalent to 4.5 mg naloxone).

Oxyargin 20 mg/10 mg
Each prolonged-release tablet contains 20 mg of oxycodone hydrochloride (equivalent to 18 mg oxycodone) and 10 mg of naloxone hydrochloride (as 10.9 mg naloxone hydrochloride dihydrate, equivalent to 9 mg naloxone).

Oxyargin 30 mg/15 mg
Each prolonged-release tablet contains 30 mg of oxycodone hydrochloride (equivalent to 27 mg oxycodone) and 15 mg of naloxone hydrochloride (as 16.35 mg naloxone hydrochloride dihydrate, equivalent to 13.5 mg naloxone).

Oxyargin 40 mg/20 mg
Each prolonged-release tablet contains 40 mg of oxycodone hydrochloride (equivalent to 36 mg oxycodone) and 20 mg of naloxone hydrochloride (as 21.8 mg naloxone hydrochloride dihydrate, equivalent to 18 mg naloxone).

The other ingredients are:
Tablet core
Oxyargin 5 mg/2.5 mg prolonged-release tablets
Oxyargin 10 mg/5 mg prolonged-release tablets
Oxyargin 20 mg/10 mg prolonged-release tablets
Oxyargin 30 mg/15 mg prolonged-release tablets
Oxyargin 40 mg/20 mg prolonged-release tablets
Polyvinyl acetate, Povidone K30, Sodium lauryl sulphate, Silica, colloidal anhydrous, Cellulose, microcrystalline, Magnesium stearate

Tablet coating
Oxyargin 5 mg/2.5 mg
Polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc.

Oxyargin 10 mg/5 mg
Polyvinyl alcohol, titanium dioxide (E171), iron oxide red (E172), macrogol 3350, talc.

Oxyargin 20 mg/10 mg
Polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc.

Oxyargin 30 mg/15 mg
Polyvinyl alcohol, titanium dioxide (E171), iron oxide yellow (E172), macrogol 3350, talc.

Oxyargin 40 mg/20 mg
Polyvinyl alcohol, titanium dioxide (E171), iron oxide red (E172), macrogol 3350, talc.

What Oxyargin looks like and contents of the pack

Oxyargin 5 mg/2.5 mg
White, round, biconvex prolonged-release tablet with a diameter of 4.7 mm and a height of 2.9 - 3.9 mm.

Oxyargin 10 mg/5 mg
Pink, oblong, biconvex prolonged-release tablet with break scores on both sides, with a length of 10.2 mm, a width of 4.7 mm and a height of 3.0 - 4.0 mm.
The tablet can be divided into equal doses.

Oxyargin 20 mg/10 mg
White, oblong, biconvex prolonged-release tablet with break scores on both sides, with a length of 11.2 mm, a width of 5.2 mm and a height of 3.3 - 4.3 mm.

The tablet can be divided into equal doses.

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

Oxyargin 40 mg/20 mg
Pink, oblong, biconvex prolonged-release tablet with break scores on both sides, with a length of 14.2 mm, a width of 6.7 mm and a height of 3.6 - 4.6 mm
The tablet can be divided into equal doses.

Oxyargin is available in:
Child-resistant blisters of 10, 14, 20, 28, 30, 50, 56, 60, 90, 98 and 100 prolonged-released tablets or
Bottles with child-resistant screw cap containing 50, 100 or 250 prolonged-released tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Mylan, Potters Bar, EN6 1TL, United Kingdom

Manufacturer
Develco Pharma GmbH, Grienmatt 27, Schopfheim, 79650, Germany

This leaflet was last revised in 05/2022