ZENTIVA

Package Leaflet: Information for the user

Myloxifin 5 mg/2.5 mg prolonged-release tablets
Myloxifin 10 mg/5 mg prolonged-release tablets
Myloxifin 20 mg/10 mg prolonged-release tablets
Myloxifin 40 mg/20 mg prolonged-release tablets

oxycodone hydrochloride/naloxone 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 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 Myloxifin is and what it is used for

This medicine has been prescribed for you for the treatment of severe pain, which can be adequately managed only with opioid analgesics.
It contains 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. Naloxone hydrochloride is added to counteract constipation.

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

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

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

These tablets are only for use in adults.

2. What you need to know before you take Myloxifin

Do not take Myloxifin
- 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 prescriber before taking this medicine:
- if you are or anyone in your family have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- 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.
- 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 Myloxifin 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 are elderly or debilitated (weak),
- if you have paralytic ileus (a type of bowel obstruction) caused by opioids,
- if you have kidney impairment,
- if you have mild liver impairment,
- if you have severe lung impairment (i.e. reduced breathing capacity),
- if you suffer from a condition that is accompanied by common respiratory interruptions and makes you feel sleepy during the day (sleep apnoe),
- 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),
- if your adrenal glands are not producing enough hormones (adrenal insufficiency, or 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.

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.

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 Myloxifin.

Taking this medicine regularly, particularly for a long time, can lead to addiction and may result in life-threatening overdose. If you have concern that you may become dependent on Myloxifin, it is important that you consult your doctor. 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.

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.

Tell your doctor in case you have cancer associated to peritoneal metastases or beginning bowel obstruction in advanced stages of digestive and pelvic cancers.

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

How to use Myloxifin 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 Myloxifin
If you have been using high doses of another opioid, withdrawal symptoms may occur when you initially switch to Myloxifin 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. Myloxifin is not suitable for withdrawal treatment.

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

You may notice remnants of the prolonged-release tablet in your stools. Do not be alarmed, as the active substances (oxycodone hydrochloride and naloxone hydrochloride) have already been released in the stomach and gut, and absorbed into your body.

Incorrect use of Myloxifin

These tablets are not suitable for withdrawal treatment.

Myloxifin 5 mg/2.5 mg
The tablet must be swallowed whole and not be divided, broken, chewed or crushed.

Myloxifin 10 mg/5mg, 20 mg/10 mg and 40 mg/20 mg
The tablet 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 Myloxifin than you should").

Abuse
Myloxifin 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 Myloxifin because it contains the ingredient naloxone. Pre-existing withdrawal symptoms may be made worse.

Misuse
You should never misuse Myloxifin 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.

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

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

If you take these tablets at the same time as you take other medicines, the effect of these tablets or the other medicine may be changed. Tell your doctor if you are taking:
- other potent painkillers (opioids),
- sleep medication and tranquilisers (sedatives, hypnotics),
- medicines to treat depression (antidepressants),
- medicines used to treat allergies, travel sickness or nausea (antihistamines or antiemetics),
- medicines to treat psychiatric or mental disorders (phenothiazines, neuroleptics, antipsychotics),
- muscle relaxants,
- medicines to treat Parkinson's disease,
- 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, erythromycin or telithromycin),
- antifungal medicines of the azole type (e.g. ketoconazole, voriconazole, itraconizole or posaconizole),
- a specific type of medicine known as a protease inhibitor used to treat HIV (examples include ritonavir indinavir, nelfinavir or saquinavir),
- cimetidine (a medicine for 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),
- a herbal remedy called St John's Wort (also known as Hypericum perforatum)
- quinidine (a medicine to treat an irregular heartbeat).

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

Myloxifin with food and drink and alcohol
Drinking alcohol whilst taking Myloxifin 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 Myloxifin.

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

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
Do not take Myloxifin 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 Myloxifin during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Use of Myloxifin 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
Do not take Myloxifin while you are breastfeeding as oxycodone passes into breast milk and will affect your baby.

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

Myloxifin has 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.

3. How to take Myloxifin

Your prescriber should have discussed with you, how long the course or 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.

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

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

hours. Do not break, chew or crush the tablets. Taking broken, chewed or crushed tablets may lead to the absorption of a potentially lethal dose of oxycodone hydrochloride (see section 3 "If you take more Myloxifin than you should").

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

For the treatment of pain

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 Myloxifin 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, Myloxifin 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 Myloxifin 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 Myloxifin, you probably may need a rapid-acting painkiller. Myloxifin is not suitable for this. In this case, please talk to your doctor.

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

For the treatment of pain
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 impairment
If you have an impairment of your kidney function or a mild impairment of your liver function, your attending doctor will prescribe Myloxifin with special caution. If you have a moderate or severe impairment of liver function, Myloxifin must not be used (see also section 2 "Do not take Myloxifin" and "Warnings and precautions").

Use in children and adolescents below 18 years of age
Myloxifin 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, Myloxifin use in children and adolescents under 18 years of age is not recommended.

Method of administration
For oral use.
Take Myloxifin 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).

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

Myloxifin 10 mg/5 mg, 20 mg/10 mg and 40 mg/20 mg
You should take Myloxifin with sufficient liquid (½ glass of water). The tablet can be divided into equal doses. The tablet 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 Myloxifin for any longer than you need to. If you are on long-term treatment with Myloxifin, your doctor should regularly check whether you still need Myloxifin.

If you take more Myloxifin than you should
If you have taken more than the prescribed dose of Myloxifin you must inform your doctor immediately.
An overdose may result in:
- narrowed pupils,
- slow and shallow breathing (respiratory depression),
- drowsiness up to loss of consciousness,
- low muscle tone (hypotonia),
- reduced pulse rate, and
- 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 Myloxifin
If you forget to take Myloxifin or if you take a dose lower than the one prescribed, you may not feel any painkilling effect.
If you 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 Myloxifin
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.

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 three sections treatment of pain, 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 exhaustion, a feeling of unusual weakness
- a feeling of dizziness or 'spinning', headache, drowsiness
- vertigo
- hot flushes
- abdominal pain, constipation, diarrhoea, dry mouth, indigestion, vomit (be 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
- epileptic seizures (especially in persons with epileptic disorder or predisposition to seizures), difficulties to concentrate, speech disorder, fainting, shaking
- 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
- weight loss
- injuries from accidents
- reduced sexual drive
- lack of energy
- thirst
- altered taste

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

Not known (frequency cannot be estimated from the available data)
- euphoric mood, hallucinations, nightmares
- tingling skin (pins and needles), severe drowsiness
- shallow breathing
- belching
- difficulties in passing urine
- erectile dysfunction
- dependence and addiction (see section "How do I know if I am addicted?")

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), drug dependence
- impaired concentration, migraines, increased muscle tension, involuntary muscle contractions, reduced sensitivity to pain or touch, abnormal coordination
- difficulties in hearing
- vocal changes (dysphonia)
- difficulties in swallowing, a condition where the bowel stops working properly (ileus), mouth ulcers, sore gums
- dry skin
- swelling due to water retention, drug tolerance
- flushing of skin
- a decrease in sex hormone levels which may affect sperm production in men or the menstrual cycle in females

Rare (may affect up to 1 in 1,000 people)
- infections such as cold sores or herpes (which may cause blisters around the mouth or genital area)
- increased appetite
- black (tarry) stools, bleeding gums
- itching rash (urticaria)

Not known (frequency cannot be estimated from the available data)
- acute generalised allergic reactions (anaphylactic reactions)
- problems with bile flow
- a problem affecting a valve in the intestines that may cause severe upper abdominal pain (sphincter of Oddi dysfunction)
- absence of menstrual periods
- withdrawal symptoms in the newborn
- tooth decay
- aggression
- an increase in sensitivity to pain
- dependence and addiction (see section "How do I know if I am addicted?")

Drug Withdrawal
When you stop taking Myloxifin, 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 Myloxifin, 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

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 MHRA 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 Myloxifin

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 Myloxifin contains

The active substances are oxycodone hydrochloride and naloxone hydrochloride.

Myloxifin 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 2.74 mg naloxone hydrochloride dihydrate, equivalent to 2.25 mg naloxone).

Myloxifin 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).

Myloxifin 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).

Myloxifin 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
Polyvinyl acetate, Povidone K30, Sodium lauryl sulphate, Silica, colloidal anhydrous, Cellulose, microcrystalline, Magnesium stearate

Tablet coating
Polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc.
Myloxifin 10 mg/5 mg and 40 mg/20mg also contains iron oxide red (E172)

What Myloxifin looks like and contents of the pack

Myloxifin 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.

Myloxifin 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.

Myloxifin 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.

Myloxifin 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.

Myloxifin is available in:
Child-resistant blisters of 10, 14, 20, 28, 30, 50, 56, 60, 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 and Manufacturer

Marketing Authorisation Holder:
Zentiva Pharma UK Limited
12 New Fetter Lane
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Manufacturer:
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