

Package leaflet: Information for the patient

***MXL*[®] 30 mg, 60 mg, 90 mg, 120 mg, 150 mg and 200 mg prolonged-release capsules** Morphine sulfate

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 *MXL* capsules are and what they are used for
2. What you need to know before you take *MXL* capsules
3. How to take *MXL* capsules
4. Possible side effects
5. How to store *MXL* capsules
6. Contents of the pack and other information

1. What *MXL* capsules are and what they are used for

These capsules have been prescribed for you by your doctor to relieve severe pain over a period of 24 hours. They contain the active ingredient morphine which belongs to a group of medicines called strong analgesics or ‘painkillers’.

2. What you need to know before you take *MXL* capsules

Do not take *MXL* capsules if:

- you are allergic to morphine or any of the other ingredients of the capsules (see section 6);
- you have breathing problems, such as obstructive airways disease, respiratory depression, or severe asthma. Your doctor will have told you if you have these conditions. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected;
- you have a head injury that causes a severe headache or makes you feel sick. This is because the capsules may make these symptoms worse or hide the extent of the head injury;
- you have a condition where the small bowel (part of your gut) 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;
- you have recent onset liver disease;
- you are taking a type of medicine known as a monoamine oxidase inhibitor (examples include tranlycypromide, phenelzine, isocarboxazid, moclobemide and linezolid), or you have taken this type of medicine in the last two weeks;
- the patient is under one year of age.

If you are going to have an operation, please tell the doctor at the hospital that you are taking these capsules.

Warnings and precautions

Talk to your doctor or pharmacist before taking these capsules if you:

- have breathing problems, such as severe bronchial asthma or impaired lung function. Your doctor will have told you if you have these conditions. Symptoms may include breathlessness and coughing;

- have an under-active thyroid gland (hypothyroidism), kidney or long-term liver problems as you may need a lower dose;
- have a severe headache or feel sick as this may indicate that the pressure in your skull is increased;
- suffer from seizures, fits or convulsions;
- have low blood pressure;
- have a severe heart problem after long-term lung disease (severe cor pulmonale);
- have inflammation of the pancreas (which causes severe pain in the abdomen and back) or problems with your gall bladder;
- have an inflammatory bowel disorder;
- you suffer from constipation;
- have prostate problems;
- have increased sensitivity to pain despite the fact that you are taking increasing doses (hyperalgesia). Your doctor will decide whether you will need a change in dose or a change in strong analgesic (“painkiller”), (see section 2);
- experience weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. This may be a symptom of the adrenal glands producing too little of the hormone ‘cortisol’, and you may need to take a hormone supplement;
- have loss of libido, impotence, cessation of menstruation. This may be because of decreased sex hormone production;
- have previously been dependent on drugs or alcohol. Also tell your doctor if you feel that you are becoming dependent on this medicine while you are using it. You may have started to think a lot about when you can take the next dose, even if you do not need it for the pain;
- have withdrawal (abstinence) symptoms or dependence. The most common abstinence symptoms are mentioned in section 3. If this occurs, your doctor may change the type of medicine or the times between doses.

This medicine may cause breathing problems or worsen already existing problems while sleeping. These problems may include pauses in breathing during sleep, being awoken by shortness of breath, difficulty staying asleep or excessive daytime drowsiness. If you or someone else observes these symptoms contact your doctor. Your doctor may want to lower your dose.

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

Other medicines and *MXL* capsules

Concomitant use of *MXL* capsules and sedative medicines, such as benzodiazepines or related drugs, increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe *MXL* capsules together with sedative medicines, the dosage and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dosage recommendation closely. It could be helpful to inform friends or relatives to be aware of signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

If you are taking or have recently taken any other medicines, or might take any other medicines please tell your doctor or pharmacist. If you take these capsules with some other medicines, the effect of the capsules or the other medicine may be changed.

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

Tell your doctor or pharmacist if you are taking any of the medicines mentioned below:

- medicines to help you sleep (for example tranquillisers, hypnotics or sedatives);
- medicines to treat psychiatric or mental disorders (such as phenothiazines);
- muscle relaxants;
- medicines to treat high blood pressure;
- Some medicines used to treat blood clots (e.g. clopidogrel, prasugrel, ticagrelor) may have delayed and decreased effect when taken together with morphine;
- cimetidine to treat stomach ulcers, indigestion or heartburn;
- other strong analgesics or ‘painkillers’ (such as buprenorphine, nalbuphine or pentazocine);
- rifampicin to treat tuberculosis;
- ritonavir to treat HIV;
- gabapentin to treat epilepsy or neuropathic pain (pain due to nerve problems).

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

Taking *MXL* capsules with alcohol

Drinking alcohol whilst taking *MXL* capsules 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 *MXL* capsules.

Pregnancy, breastfeeding 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.

Prolonged use of morphine during pregnancy may cause withdrawal symptoms in newborns, which should be treated by a doctor. Withdrawal (abstinence) symptoms in babies born to mothers who have used *MXL* capsules in pregnancy may include high-pitched crying, irritability and restlessness, shaking (tremor), feeding difficulties and sweating.

Driving and using machines

These capsules may cause a number of side effects such as drowsiness which could affect your ability to drive or use machinery (see section 4 for a full list of side effects). These are usually most noticeable when you first start taking the capsules, 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.

***MXL* capsules contain sodium**

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

3. How to take *MXL* capsules

Always take the capsules exactly as your doctor or pharmacist has told you. The label on your medicine will tell you how many capsules to take and how often. Check with your doctor or pharmacist if you are not sure.

Swallow your capsules whole with a glass of water. If you prefer, you can open your capsules and sprinkle the contents on to cold soft food, such as yogurt. **Do not crush, dissolve or chew the capsule contents.**

MXL capsules are designed to work properly over 24 hours. If the capsule contents are crushed, dissolved or chewed, the entire 24-hour dose may be absorbed rapidly into your body. This can be dangerous, causing serious problems such as an overdose, which may be fatal.

You should take your capsules every 24 hours. For instance, if you take a capsule at 8 o'clock in the morning, you should take your next capsule at 8 o'clock the next morning.

You must only take the capsules by mouth.

Adults

The usual starting dose is one 60 mg capsule every 24 hours. However, the dose will depend on your age, weight and the severity of your pain. If you are elderly or weigh less than 70 kg your doctor may suggest a starting dose of one 30 mg capsule every 24 hours. Your doctor will decide how many capsules you should take.

Children over one year of age

Children over one year of age can take these capsules. The required dose will depend on their weight and severity of pain. This should be discussed with your doctor or pharmacist.

If you find that you are still in pain whilst taking these capsules discuss this with your doctor.

Do not exceed the dose recommended by your doctor. You should check with your doctor or pharmacist if you are not sure.

If you take more MXL capsules than you should or if someone accidentally swallows your capsules

Call your doctor or hospital straight away as you may need emergency treatment in hospital. People who have taken an overdose may feel very sleepy, sick, dizzy or get pneumonia from inhaling vomit or foreign matter (symptoms may include breathlessness, cough and fever). People who have taken an overdose may also have breathing difficulties leading to unconsciousness, or even death.

When seeking medical attention make sure that you take this leaflet and any remaining capsules with you to show to the doctor.

If you forget to take MXL capsules

If you remember within 16 hours of the time your capsule was due, take your capsule straight away. Take your next capsule at your normal time. If you are more than 16 hours late, please call your doctor for advice. Do not take a double dose to make up for a forgotten capsule.

If you stop taking MXL capsules

Do not stop treatment with these capsules unless agreed with your doctor. If you want to stop the treatment with these capsules, ask your doctor how to slowly decrease the dose so you avoid abstinence symptoms. Abstinence (withdrawal) symptoms may include body aches, tremors, diarrhoea, stomach pain, nausea, flu-like symptoms, fast heartbeat and large pupils. Psychological symptoms include an intense feeling of dissatisfaction, anxiety and irritability.

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.

All medicines can cause allergic reactions, although serious allergic reactions are uncommon. 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.

The most serious side effect is a condition where you breathe more slowly or weakly than expected (respiratory depression). **Tell your doctor immediately** if this happens to you.

As with all strong painkillers, there is a risk that you may become addicted or reliant on these capsules.

The following side effects may also occur:

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

- Constipation (your doctor can prescribe a laxative to overcome this problem).
- Feeling sick.

Common side effects (may affect up to 1 in 10 people)

- Drowsiness (this is most likely when you first start taking your capsules or when your dose is increased, but it should wear off after a few days).
- Dry mouth, loss of appetite, abdominal pain or discomfort.
- Vomiting (being sick). (This should normally wear off after a few days. However, your doctor can prescribe an anti-vomiting medicine if it continues to be a problem).
- Dizziness, headache, confusion, difficulty in sleeping.
- A feeling of unusual weakness.
- Generally feeling unwell, tiredness.
- Involuntary muscle contractions.
- Rash or itchy skin.
- Sweating.

Uncommon side effects (may affect up to 1 in 100 people)

- Difficulty in breathing (possibly due to fluid on the lungs) or wheezing.
- A condition where the bowel does not work properly (ileus).
- Changes in taste, indigestion.
- A feeling of dizziness or 'spinning', fainting, seizures, fits or convulsions.
- Agitation, mood changes, hallucinations, a feeling of extreme happiness.
- Unusual muscle stiffness.
- Tingling or numbness.
- Difficulty in passing urine.
- Low blood pressure, facial flushing (redness of the face).
- Palpitations.
- Swelling of the hands, ankles or feet.
- Hives.
- A worsening in liver function tests (seen in a blood test).
- Blurred vision.
- Muscle spasms.

Not known (frequency cannot be estimated from available data)

- Problems with breathing during sleep (sleep apnoea syndrome)
- Unpleasant or uncomfortable mood, abnormal thoughts.
- An increased sensitivity to pain.
- Reduction in size of the pupils in the eye.
- A fast or slow heartbeat.
- High blood pressure.
- Decreased cough reflex.
- Colicky abdominal pain or discomfort, an increase in the severity of symptoms associated with

inflammation of the pancreas (severe pain in the abdomen and back).

- Impotence, decreased sexual drive, absence of menstrual periods.
- Withdrawal symptoms or dependence (See section 3 “If you stop taking *MXL* capsules”).
- Withdrawal symptoms in babies born to mothers who have used *MXL* capsules in pregnancy (See section 2 ‘Pregnancy, breastfeeding and fertility’).

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 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 *MXL* capsules

Keep this medicine out of sight and reach of children.

Do not use any capsules after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.

Do not store your capsules above 25°C.

Do not take your capsules if they are broken or crushed as this can be dangerous and can cause serious problems such as overdose.

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What *MXL* capsules contain

The active ingredient is morphine sulfate. Each capsule contains 30 mg, 60 mg, 90 mg, 120 mg, 150 mg or 200 mg of morphine sulfate.

The other ingredients are:

- Hydrogenated vegetable oil
- Macrogol
- Talc
- Magnesium stearate
- Gelatin (contains Sodium dodecyl sulfate)
- Shellac
- Iron oxide (E172)
- Propylene glycol
- Titanium dioxide (E171)

The capsules also contain the following colourants:

30 mg, 60 mg & 120 mg - Indigo carmine (E132)

90 mg - Erythrosine (E127)

150 mg - Erythrosine (E127) and indigo carmine (E132)

What *MXL* capsules look like and contents of the pack

The capsules are marked MS OD followed by the strength (e.g. 30, 60 etc).

The capsules are coloured as follows: 30 mg - light blue, 60 mg - brown, 90 mg - pink, 120 mg - olive, 150 mg - blue, 200 mg - rust.

In each box there are 28 capsules.

Marketing Authorisation Holder and Manufacturer

The capsules are made by Bard Pharmaceuticals Limited for the marketing authorisation holder Napp Pharmaceuticals Limited, both at Cambridge Science Park, Milton Road, Cambridge CB4 0GW, UK.

This leaflet is also available in large print, Braille or as an audio CD. To request a copy, please call the RNIB Medicine Information line (free of charge) on:

0800 198 5000

You will need to give details of the product name and reference number.
These are as follows:

Product name: MXL prolonged-release capsules
Reference number: 16950/0042

This leaflet was last revised in February 2021.

MXL[®] capsules are protected by European Patent (UK) Nos. 0636370 and 0654263.

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