

MORPHINE MR MYLAN

Modified release tablets

Contains the active ingredient morphine sulfate pentahydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MORPHINE MR MYLAN. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking MORPHINE MR MYLAN against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What MORPHINE MR MYLAN is used for

The name of your medicine is MORPHINE MR MYLAN. It contains the active ingredient morphine sulfate pentahydrate. Morphine belongs to a group of medicines called opioid analgesics. It acts in the central nervous system by blocking pain and your emotional response to pain.

MORPHINE MR MYLAN is used to treat chronic severe pain.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Opioid analgesics such as morphine sulphate have been used to treat chronic cancer pain for many years. In most cases physical dependence does not occur. However, over time your body becomes used to taking morphine, so if you suddenly stop taking your MORPHINE MR MYLAN tablets you may experience some symptoms of withdrawal.

It is important that you discuss this issue with your doctor and take the medicine exactly as directed by your doctor.

This medicine is available only with a doctor's prescription.

Before you take MORPHINE MR MYLAN

When you must not take it

Do not take MORPHINE MR MYLAN if you have an allergy to:

- any medicine containing morphine
- any of the ingredients listed at the end of this leaflet.
- other opioid analgesics.

Some of the symptoms of an allergic reaction may include:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- fainting or hayfever-like symptoms.

Do not take MORPHINE MR MYLAN if you have or have had any of the following:

- shallow breathing or other breathing problems, such as severe asthma, respiratory depression, impaired lung function, chronic bronchitis or other obstructive airway disease
- severely drowsy or a reduced level of consciousness
- irregular, rapid or change to your heart beat
- heart disease due to long term lung disease
- just consumed a large amount of alcohol, regularly consume large amounts of alcohol or have confusion and shaking due to alcohol withdrawal
- long lasting pain not due to disease progression and have a history of substance and alcohol abuse
- fits, convulsions or seizures
- head injury, brain tumour, increased pressure in your head or spine
- severe kidney or liver disease or a disease of the brain caused by liver disease
- sudden, severe abdominal pain which may be accompanied by bloating, cramps or vomiting
- a condition where your stomach empties more slowly than it should or your small bowel does not work properly
- an obstruction of the bowel or a condition where it could occur

- about to have an operation or have had one within the last 24 hours including surgery on your spine for pain relief
- taking medicine for depression called a ‘monoamine oxidase inhibitor’ or have taken any in the last two weeks

Do not take this medicine if you are pregnant or intend to become pregnant whilst taking this medication.

MORPHINE MR MYLAN tablets are not recommended to be taken during pregnancy. It may affect your developing baby if you take it during pregnancy. Your doctor will discuss the risks of using this medicine if you are pregnant.

Do not give this medicine to a child under one year of age or weighing less than 25kg.

Safety and effectiveness in children younger than one year of age or weighing less than 25kg have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Please note if you are lactose intolerant that some of the strengths of this medicine also contain lactose (except for 100 mg).

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have any medical conditions, especially the following:

- low blood pressure, for example due to low blood volume
- increased prostate size or difficulty passing urine

- narrowing of the urinary bladder tract
- problems or recent surgery of your gall bladder or bile duct
- biliary tract disease
- inflammation of the pancreas
- adrenal glands not working properly or underactive adrenal gland
- underactive thyroid gland
- epilepsy (a disease that causes fits, convulsions or seizures), convulsive disorders
- acute abdominal pain, constipation or diarrhoea
- inflammatory bowel disease or recent abdominal surgery
- galactose intolerance, lactase deficiency or have problems with glucose-galactose absorption
- an addiction or history of abuse of alcohol or drugs
- acute chest pain or sickle cell disease
- impaired respiratory function, adrenocortical insufficiency, hypotension with hypovolaemia, pancreatitis
- liver or kidney disease

Tell your doctor if you are breastfeeding or planning to breastfeed.

Morphine can pass into the breast milk and can affect the baby. Your doctor can discuss with you the risks and benefits involved.

This medicine is not recommended to be taken during labour.

Morphine given to the mother during labour can cause breathing problems in the newborn.

Tell your doctor if you are planning to have surgery, an anaesthetic or are currently receiving or planning to receive dental treatment.

If you have not told your doctor about any of the above, tell them before you start taking MORPHINE MR MYLAN.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines or dietary supplements, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and MORPHINE MR MYLAN may interfere with each other. These include:

- medicines to treat depression, psychiatric or mental disorders and anxiety.
- Medicines for depression belonging to a group called monoamine oxidase inhibitors must be stopped 14 days before MORPHINE MR MYLAN tablets are taken.
- medicines to help you sleep
- medicines to put you to sleep during an operation or procedure
- medicines to relax your muscles
- medicines to prevent or relieve the symptoms of allergy such as antihistamines
- propranolol or other medicines to lower blood pressure
- gabapentin or barbiturates, medicines to treat seizures
- medicines to thin the blood e.g. coumarin derivatives such as warfarin
- buprenorphine, nalbuphine, pentazocine
- medicines used to relieve heartburn or treat stomach ulcers such as cimetidine or antacids (take antacids at least 2 hours after taking MORPHINE MR MYLAN tablets)
- alkalinising agents used to manage disorders associated with low pH
- medicines to treat Parkinson's disease
- medicines to stop nausea or vomiting e.g. metoclopramide or prochlorperazine
- rifampicin, a medicine to treat tuberculosis

- other pain relievers including other opioids
- alcohol
- medicines to treat HIV infection and AIDS e.g. ritonavir or zidovudine.
- amphetamines, such as stimulant or medicines to treat ADHD
- methocarbamol (Robaxin)

These medicines may be affected by MORPHINE MR MYLAN or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take MORPHINE MR MYLAN

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

MORPHINE MR MYLAN tablets must be swallowed whole. MORPHINE MR MYLAN tablets must not be chewed, crushed or dissolved.

MORPHINE MR MYLAN tablets are only designed to work properly if

swallowed whole. The tablets may release all their contents at once if broken, chewed, crushed or dissolved which can be dangerous and cause serious problems, such as an overdose or even death.

If you have trouble swallowing your tablets whole, talk to your doctor.

You must only take MORPHINE MR MYLAN tablets by mouth.

Taking this medicine in a manner other than that prescribed by your doctor can be harmful to your health.

When to take it

MORPHINE MR MYLAN tablets should be taken every 12 hours. MORPHINE MR MYLAN tablets must be taken regularly to control the pain. Taking MORPHINE MR MYLAN tablets at regular time intervals means that the onset of pain is prevented.

It is important to take the tablets at the times you have been told to. If, however, you begin to experience pain and you are taking your MORPHINE MR MYLAN as prescribed ('breakthrough pain'), contact your doctor as your dosage may have to be reviewed.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

If you stop taking this medicine suddenly, your pain may worsen and you may experience withdrawal symptoms such as:

- body aches
- loss of appetite, nausea, stomach cramps or diarrhoea
- fast heart rate
- sneezing or runny nose
- chills, tremors, shivering or fever
- trouble sleeping
- increased sweating and yawning
- weakness
- nervousness or restlessness

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If you forget to take a dose, contact your doctor for advice.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much MORPHINE MR MYLAN.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include becoming drowsy, tired, confused, lack muscle tone, have cold or clammy skin, have constricted pupils, have a very low blood pressure or slow heart rate, experience difficulties in breathing and possibly become unconscious or even die. When seeking medical attention, take this leaflet and any remaining tablets with you to show the doctor. Also, tell them about any other medicines or alcohol which have been taken.

While you are using MORPHINE MR MYLAN

Things you must do

Take MORPHINE MR MYLAN tablets exactly as your doctor has prescribed.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking MORPHINE MR MYLAN.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Tell your doctor if your pain is getting worse or you are having more frequent breakthrough pain.

Also tell your doctor if you are having any problems or difficulties while you are being treated with MORPHINE MR MYLAN tablets.

Tolerance to morphine may develop which means that the effect of the medicine may decrease. If this happens, your doctor may review your dose so that you get adequate pain relief.

Things you must not do

Do not take MORPHINE MR MYLAN to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

Over time your body may become used to you taking morphine so if you stop taking it suddenly, your pain may worsen and you may experience withdrawal symptoms. This is called physical dependence.

If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Things to be careful of

Be careful driving or operating machinery until you know how MORPHINE MR MYLAN affects you.

Ask your doctor's advice about whether or not it will be safe for you to drive or operate any machinery whilst taking MORPHINE MR MYLAN. It may cause drowsiness, dizziness, hallucinations, confusion, vision problems or may affect alertness.

Be careful when drinking alcohol while you are taking this medicine.

You may feel drowsy when you begin to take MORPHINE MR MYLAN tablets. If you drink alcohol, the drowsiness may be worse.

Be careful if you are elderly, unwell or taking other medications.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Tell your doctor if you suffer from nausea or vomiting when taking MORPHINE MR MYLAN tablets.

If you vomit 2-3 hours after your dose your pain may come back as you will not have absorbed your morphine. If this happens speak to

your doctor. Your doctor may prescribe some medicine to help stop you vomiting.

Tell your doctor if taking MORPHINE MR MYLAN tablets causes constipation.

You should speak to your doctor about your diet and the proper use of laxatives.

There is potential for abuse of morphine and the development of addiction to morphine. It is important that you discuss this issue with your doctor.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MORPHINE MR MYLAN.

This medicine helps most people with severe pain, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- constipation
- sweating
- nausea or vomiting
- loss of appetite
- dry mouth or changes in taste
- sweating
- facial flushing
- trouble sleeping
- trouble with your balance
- new problems with your eyesight

- skin rash, redness in the face or itching
- irregular menstrual periods, sexual problems or other hormonal changes
- muscle twitching or muscle tightness or stiffness
- swelling, not limited to the legs or ankles
- feeling pain from something that is ordinarily painless, for example, bedsheets being pulled across the skin

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- breathing difficulties
- stomach discomfort or cramps, indigestion or abdominal pain
- abnormal thinking or changes in mood
- drowsiness, fainting or dizziness especially when standing up
- slow or noticeable heartbeats
- headache, confusion, nervousness or hallucinations
- unusual weakness or loss of strength
- fatigue, generally feeling unwell
- changes in passing urine such as the volume passed, pain or feeling the need to urinate urgently

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- your breathing slows or weakens
- you have an allergic reaction: shortness of breath, wheezing, shallow or difficult breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin
- seizures, fits or convulsions

- fast or irregular heartbeats
- you have sickle cell disease and you experience painful or rapid breathing, fever, cough, or bluish changes to the colour of your skin.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After using MORPHINE MR MYLAN

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store MORPHINE MR MYLAN or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

10 mg tablets

Buff coloured, biconvex, smooth, round, film coated tablets with 10 on one face

30 mg tablets

Violet coloured, biconvex, smooth, round, film coated tablets with 30 on one face

60 mg tablets

Orange coloured, biconvex, smooth, round, film coated tablets with 60 on one face

100 mg tablets

Grey coloured, biconvex, smooth, round, film coated tablets with 100 on one face

Available in blister packs of 20, 28 or 60 tablets.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 10, 30, 60 or 100 mg of morphine sulfate pentahydrate as the active ingredient.

It also contains the following inactive ingredients:

- lactose monohydrate (except the 100 mg)
- hyetellose
- hypromellose
- povidone
- purified talc
- magnesium stearate

The tablet coatings contain a different colourant for each strength, as follows:

- 10 mg: Opadry buff OY-3607
- 30 mg: Opadry violet OY-6708
- 60 mg: Opadry orange OY-3533
- 100 mg: Opadry grey OY-8238

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes. The 100 mg strength is lactose-free.

The 10mg, 30mg and 60mg tablets contain sugars (as lactose monohydrate).

Sponsor

Southern Cross Pharma Pty Ltd

Suite 5/118 Church St
Hawthorn VIC 3122

Distributor

MORPHINE MR MYLAN is distributed in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

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MORPHINE MR MYLAN 10 mg tablets (blisters): AUST R 225421.

MORPHINE MR MYLAN 30 mg tablets (blisters): AUST R 225422.

MORPHINE MR MYLAN 60 mg tablets (blisters): AUST R 225423.

MORPHINE MR MYLAN 100 mg tablets (blisters): AUST R 225424.

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