

MORPHINE MR MYLAN

Modified Release tablets

Contains the active ingredient morphine sulfate pentahydrate

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is MORPHINE MR MYLAN. It contains the active ingredient morphine sulfate (as pentahydrate)

It 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 this medicine for another reason.

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

How it works

Opioid analgesics such as morphine sulphate have been used to treat chronic cancer pain for many years. In most cases addiction 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.

Use in children

This medicine must not be used in children under one year of age or weighing less than 25 kg. Safety and effectiveness has not been established in children under one year of age or weighing less than 25kg.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have or have had any of the following:**
- **shallow breathing or other breathing problems, such as severe asthma, impaired lung function or chronic bronchitis**

- **severely drowsy or a reduced level of consciousness**
- **irregular or rapid heart beats**
- **heart disease**
- **regularly drinking large amounts of alcohol or have confusion and shaking due to stopping drinking alcohol**
- **long lasting pain not due to disease progression and have a history of substance and alcohol abuse**
- **fits or convulsions**
- **head injury, brain tumour, increased pressure in your head or spine**
- **are about to have an operation or have had one within the last 24 hours**
- **severe kidney or liver disease or a disease of the brain caused by liver disease**
- **severe abdominal pain with bloating, cramps or vomiting**
- **a condition where your stomach empties more slowly than it should, your small bowel does not work properly or you have just had an operation on your abdomen**
- **taking medicine for depression called a 'monoamine oxidase inhibitor' or have taken any in the last two weeks**
- **You are pregnant.**
- **MORPHINE MR MYLAN may affect your developing baby if you take it during pregnancy.**
- **Like most medicines of this kind, MORPHINE MR MYLAN is not recommended to be taken during pregnancy. Your doctor will discuss the risks and benefits of using it if you are pregnant.**
- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.
- **You are hypersensitive or have had an allergic reaction to MORPHINE MR MYLAN, other opioid analgesics, or any of the ingredients listed at the end of this leaflet.**
Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting or hayfever-like symptoms.
- **If you think you are having an allergic reaction do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.**
- Please note if you are lactose intolerant that some of the strengths of this medicine also contain lactose (except for 100 mg).

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
- any other medicines

- any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - low blood pressure including from having low blood volume
 - increased prostate size or difficulty passing urine
 - problems or recent surgery of your gall bladder or bile duct
 - inflammation of the pancreas
 - adrenal glands not working properly
 - underactive thyroid gland
 - acute abdominal pain
 - inflammatory bowel disease or recent abdominal surgery.
 3. This medicine is not recommended to be taken during labour.
Morphine given to the mother during labour can cause breathing problems in the newborn.
 4. You are currently breast-feeding or you plan 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.
 5. You are planning to have surgery or an anaesthetic.
 6. You are currently receiving or are planning to receive dental treatment.
 7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with MORPHINE MR MYLAN. These include:

- medicines to treat depression, psychiatric or mental disorders. 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 to treat seizures
- medicines to thin the blood e.g. coumarin derivatives such as warfarin
- 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)
- medicines to treat Parkinson's disease
- medicines to stop nausea or vomiting e.g. metoclopramide
- rifampicin, a medicine to treat tuberculosis

- other pain relievers including other opioids
- alcohol
- medicines to treat HIV infection
- amphetamines

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with MORPHINE MR MYLAN.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

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 for

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 missed doses.

This may increase the chance of you experiencing side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If someone takes an overdose they may become 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 taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you become pregnant while taking this medicine, tell your doctor immediately
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.
- your pain is getting worse or you are having more frequent breakthrough pain.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first 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 you need to stop taking this medicine, your doctor will gradually reduce the amount you take each day, if possible, before stopping the medicine completely.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine 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.

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

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

Standing up slowly 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.

You may suffer from nausea or vomiting when taking MORPHINE MR SCP 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.

Constipation can be caused by morphine. 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.

Possible side effects

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

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor or pharmacist if you notice any of the following.

This list includes the more common side effects.

- constipation
- drowsiness
- sweating
- dizziness
- nausea or vomiting

Other possible side effects are listed below. Tell your doctor or pharmacist as soon as possible if you notice any of the following:

- breathing difficulties
- loss of appetite
- dry mouth or changes in taste
- trouble sleeping
- new problems with your eyesight
- skin rash, redness in the face or itching
- faintness
- irregular periods or sexual problems
- muscle twitching or muscle tightness
- swelling of legs or ankles
- stomach discomfort or cramps, indigestion or abdominal pain

- abnormal thinking or changes in mood
- slow or noticeable heartbeats
- headache, confusion or hallucinations
- unusual weakness or loss of strength
- changes in passing urine such as the volume passed, pain or feeling the need to urinate urgently.
- seizures, fits or convulsions

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to MORPHINE MR MYLAN tablets, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- 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
- hayfever-like symptoms

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, 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 this medicine 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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What MORPHINE MR MYLAN 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 (except the 100 mg)
- hyetellose
- hypromellose
- povidone
- talc – purified,
- 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.

Australian Registration Numbers

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.

Sponsor

Southern Cross Pharma Pty Ltd
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