

MORPHINE MR MYLAN modified release tablets

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using MORPHINE MR MYLAN tablets?

MORPHINE MR MYLAN tablets contain the active ingredient morphine sulfate pentahydrate. MORPHINE MR MYLAN tablets are used for the management of pain severe enough to require daily, long-term opioid treatment and for which other forms of treatment have failed or are otherwise inappropriate to provide sufficient management of pain.

For more information, see Section 1. Why am I using MORPHINE MR MYLAN tablets? in the full CMI.

2. What should I know before I use MORPHINE MR MYLAN tablets?

Do not use if you have ever had an allergic reaction to morphine or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use MORPHINE MR MYLAN tablets?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MORPHINE MR MYLAN tablets and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use MORPHINE MR MYLAN tablets?

- Your doctor will tell you exactly how much to take.
- Follow the instructions given to you by your doctor or your pharmacist.

- You must only take MORPHINE MR MYLAN tablets by mouth.

More instructions can be found in Section [4. How do I use MORPHINE MR MYLAN tablets?](#) in the full CMI.

5. What should I know while using MORPHINE MR MYLAN tablets?

<p>Things you should do</p>	<ul style="list-style-type: none"> • Remind any doctor or dentist you visit that you are using MORPHINE MR MYLAN tablets. • Tell your doctor or pharmacist if you are taking any other medicines that you use to help you relax, anything that contains alcohol (like cough syrup) or other medicines that treat pain.
<p>Things you should not do</p>	<ul style="list-style-type: none"> • Do not stop using this medicine suddenly. • Do not take more than your doctor tells you to.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> • MORPHINE MR MYLAN tablets may cause drowsiness. If affected,

	do not drive a vehicle or operate machinery.
Drinking alcohol	<ul style="list-style-type: none"> • Avoid alcohol. Alcohol may make you feel more sleepy and could increase the risk of serious side effects, such as shallow breathing with the risk of stopping breathing and loss of consciousness.
Looking after your medicine	<ul style="list-style-type: none"> • Store below 25°C. • Keep it where young children cannot reach it.

For more information, see Section [5. What should I know while using MORPHINE MR MYLAN tablets?](#) in the full CMI.

6. Are there any side effects?

MORPHINE MR MYLAN tablets may cause constipation, nausea, vomiting, dizziness, drowsiness and be habit forming if taken frequently or over long periods.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING:

Limitations of use

MORPHINE MR MYLAN tablets should only be used when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and harmful use

MORPHINE MR MYLAN tablets poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

MORPHINE MR MYLAN tablets can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting MORPHINE MR MYLAN tablets and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines while using MORPHINE MR MYLAN tablets

Using MORPHINE MR MYLAN tablets with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin

and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use; and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using MORPHINE MR MYLAN tablets.

MORPHINE MR MYLAN modified release tablets

Active ingredient: *morphine sulfate pentahydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MORPHINE MR MYLAN tablets. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MORPHINE MR MYLAN tablets.**

Where to find information in this leaflet:

- [1. Why am I using MORPHINE MR MYLAN tablets?](#)
- [2. What should I know before I use MORPHINE MR MYLAN tablets?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MORPHINE MR MYLAN tablets?](#)
- [5. What should I know while using MORPHINE MR MYLAN tablets?](#)

[6. Are there any side effects?](#)

[7. Product details](#)

1. Why am I using MORPHINE MR MYLAN tablets?

MORPHINE MR MYLAN tablets contains the active ingredient morphine sulfate pentahydrate. Morphine belongs to a group of medicines called opioid analgesics.

MORPHINE MR MYLAN tablets are indicated for the management of severe pain where:

- other treatment options have failed, are contraindicated, not tolerated or are otherwise inappropriate to provide sufficient management of pain, and
- the pain is opioid-responsive, and
- requires daily, continuous, long-term treatment.

2. What should I know before I use MORPHINE MR MYLAN tablets?

Warnings

Do not use MORPHINE MR MYLAN tablets if:

- you are allergic to morphine, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

- you have acute breathing difficulties such as bronchitis or asthma
- you have severe abdominal pain with bloating, cramps or vomiting
- you have a condition where your small bowel does not work properly
- you take medicine for depression called a 'monoamine oxidase inhibitor' or have taken any in the last two weeks
- you are pregnant or in labour.

Check with your doctor if you:

- are severely drowsy, have a reduced level of consciousness or are feeling faint or dizzy upon standing
- have heart problems or heart disease
- have low blood pressure
- have chronic lung disease
- suffer from sleep apnoea (temporarily stop breathing while you sleep)
- have just drunk a large amount of alcohol, regularly drink large amounts of alcohol or have confusion and shaking due to stopping drinking alcohol
- suffer from convulsions, fits or seizures
- have a head injury, brain tumour or increased pressure in your head
- are about to have surgery, had recent gastrointestinal surgery or have had other surgery in the last 24 hours
- have chronic liver or kidney disease

- have increased prostate size or difficulty passing urine
- have problems with your gall bladder
- have problems with or recent surgery of your bile duct
- have inflammation of the pancreas
- have adrenal glands which are not working properly
- have an underactive thyroid gland
- have a severe mental condition involving losing contact with reality or an inability to think clearly
- have an addiction or history of abuse of alcohol, opioids or other drugs.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

MORPHINE MR MYLAN tablets given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Low levels of opioid analgesics have been detected in human milk.

Addiction

You can become addicted to MORPHINE MR MYLAN tablets even if you take it exactly as prescribed. MORPHINE MR MYLAN tablets may become habit

forming causing mental and physical dependence. If abused, it may become less able to reduce pain.

Dependence

As with all other opioid containing products, your body may become used to you taking MORPHINE MR MYLAN tablets. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking MORPHINE MR MYLAN tablets suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to MORPHINE MR MYLAN tablets may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- loss of appetite, nausea, vomiting or diarrhoea
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning

- increased sweating.

3. What if I am taking other medicines?

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

Some medicines may interfere with MORPHINE MR MYLAN tablets and affect how it works.

Using MORPHINE MR MYLAN tablets with medicines that can make you feel drowsy may result in severe drowsiness, decreased awareness, breathing problems, coma and death. These medicines include:

- sleeping tablets and other sedatives (including benzodiazepines and barbiturates)
- gabapentinoids
- cannabis
- antihistamines
- anxiolytics
- general anaesthetics
- antiemetics
- antidepressants (including tricyclic antidepressants)
- antipsychotics (including phenothiazines)
- neuroleptics
- beta-blockers (medicines used to treat high blood pressure)
- other opioids
- alcohol.

MORPHINE MR MYLAN tablets may enhance the action of neuromuscular blocking agents (medicines used to relax muscles) and affect your breathing.

MORPHINE MR MYLAN tablets may increase the anticoagulant activity of coumarin and other anticoagulants (medicines used to prevent blood clots).

MORPHINE MR MYLAN tablets should not be used if you are taking non-selective monoamine oxidase inhibitors (MAOIs) or within 14 days of stopping such treatment.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MORPHINE MR MYLAN tablets.

4. How do I use MORPHINE MR MYLAN tablets?

How much to take

- Your doctor will tell you how much to take.
- Follow the instructions provided and use MORPHINE MR MYLAN tablets until your doctor tells you to stop.

When to take MORPHINE MR MYLAN tablets

- Take MORPHINE MR MYLAN tablets every 12 hours or as directed by your doctor.
- Take MORPHINE MR MYLAN tablets at about the same time each day.

How to take MORPHINE MR MYLAN tablets

Swallow MORPHINE MR MYLAN tablets whole and be careful not to break, chew, crush or dissolve the tablets.

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 which may be fatal.

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

If you begin to experience pain, tell your doctor as your dosage may have to be reviewed.

If you forget to use MORPHINE MR MYLAN tablets

You should take MORPHINE MR MYLAN tablets at the same time each day. If you miss your dose at the usual time, you may take MORPHINE MR MYLAN tablets as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

This may increase the chance of getting unwanted side effects including severe drowsiness, decreased awareness, breathing problems, coma and death.

If you use too much MORPHINE MR MYLAN tablets (overdose)

If you or someone else receive too much (overdose), and experience one or more of the symptoms below, call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you have accidentally used MORPHINE MR MYLAN tablets that was prescribed for you. If someone takes an overdose, they may experience one or more of the following symptoms:

- slow, unusual or difficult breathing
- drowsiness, dizziness or unconsciousness
- slow or weak heartbeat
- nausea or vomiting
- convulsions or fits.

If you think you or someone else may have used too much MORPHINE MR MYLAN tablets you should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

5. What should I know while using MORPHINE MR MYLAN tablets?

Things you should do

Call your doctor straight away if you:

- become pregnant
- feel your pain is getting worse.

Remind any doctor, dentist or pharmacist you visit that you are using MORPHINE MR MYLAN tablets.

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

Things you should not do

Do not stop using this medicine suddenly. If you stop taking MORPHINE MR MYLAN tablets suddenly, your pain may worsen and you may experience withdrawal symptoms.

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

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MORPHINE MR MYLAN tablets affects you.

MORPHINE MR MYLAN tablets may cause drowsiness or impair mental and/or physical ability in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may make you feel more sleepy, and could increase the risk of serious side effects, such as shallow breathing with the risk of stopping breathing and loss of consciousness.

Looking after your medicine

- Store below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If the medicine is damaged, you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal and urinary related: <ul style="list-style-type: none">• constipation• nausea or vomiting• difficulty urinating	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<p>Neurological and behavior related:</p> <ul style="list-style-type: none"> • dizziness • drowsiness • headache <p>Allergy related:</p> <ul style="list-style-type: none"> • sweating 	

Serious side effects

Serious side effects	What to do
<p>Breathing related:</p> <ul style="list-style-type: none"> • difficulty breathing or shallow breathing <p>Neurological and behaviour related:</p> <ul style="list-style-type: none"> • light-headedness, fainting or dizziness especially when standing up • changes in mood • drowsiness or feeling extremely sedated • feeling disorientated and having nightmares 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>Heart related:</p> <ul style="list-style-type: none"> ● slow or noticeable heartbeats <p>Gastrointestinal and urinary related:</p> <ul style="list-style-type: none"> ● severe stomach pain with nausea or vomiting ● difficulty urinating <p>Allergy related:</p> <ul style="list-style-type: none"> ● shortness of breath, swelling of the face, lips, tongue or other parts of the body 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What MORPHINE MR MYLAN tablets contains

Active ingredient (main ingredient)	morphine sulfate pentahydrate
Other ingredients (inactive ingredients)	Lactose monohydrate (except 100 mg) Hyetellose Povidone Magnesium stearate Purified talc Hypromellose <u>Colorants in coating:</u> 10 mg: Opadry buff OY-3607 30 mg: Opadry violet OY-6708

	60 mg: Opadry orange OY-3533 100 mg: Opadry grey OY-8238
Potential allergens	10 mg, 30 mg and 60 mg tablets contain sugars (as lactose monohydrate).

Do not take this medicine if you are allergic to any of these ingredients.

What MORPHINE MR MYLAN tablets look like

MORPHINE MR MYLAN modified release tablets are film-coated and biconvex in shape and are available in four strengths packed in blister packs of 20, 28 or 60 tablets.

MORPHINE MR MYLAN tablets 10 mg - Buff coloured, biconvex, smooth, round, film coated tablets with 10 on one face (AUST R 225421)

MORPHINE MR MYLAN tablets 30 mg - Violet coloured, biconvex, smooth, round, film coated tablets with 30 on one face (AUST R 225422)

MORPHINE MR MYLAN tablets 60 mg - Orange coloured, biconvex, smooth, round, film coated tablets with 60 on one face (AUST R 225423)

MORPHINE MR MYLAN tablets 100 mg - Grey coloured, biconvex, smooth, round, film coated tablets with 100 on one face (AUST R 225424)

Who distributes MORPHINE MR MYLAN tablets

Alphapharm Pty Ltd

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

The sponsor is:

Southern Cross Pharma Pty Ltd

Suite 5/118 Church St

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