

MS CONTIN[®] Tablets

Morphine sulfate (mor-fean sul-fate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about MS CONTIN controlled release tablets ("tablets").

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 this medicine 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 MS CONTIN tablets are taken for

MS CONTIN tablets contain morphine sulfate. Morphine belongs to a group of medicines called opioid analgesics.

MS CONTIN tablets are taken to treat chronic severe pain.

Opioid analgesics such as morphine sulfate have been used to treat chronic pain for many years.

Your doctor, however, may prescribe it for another purpose.

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

As with all strong painkillers, your body may become used to you taking MS CONTIN tablets. Taking it may result in physical dependence.

Physical dependence means that you may experience withdrawal symptoms if you stop taking morphine suddenly, so it is important to take it exactly as directed by your doctor.

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

Before you take it

When you must not take it

Do not take MS CONTIN tablets if you:

- suffer from shallow breathing or have any breathing problems such as acute asthma, impaired lung function or chronic bronchitis
- are severely drowsy or have a reduced level of consciousness
- suffer from irregular or fast heartbeats or changes in the way the heart beats
- have heart problems or heart disease including if due to long-term lung disease
- 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, increased pressure in your head or spine
- have severe abdominal pain with bloating, cramps or vomiting
- have 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

- have severe kidney or liver disease or a disease of the brain caused by liver disease
- are about to have an operation or have had one within the last 24 hours including surgery on your spine for pain relief
- are taking medicine for depression called a 'monoamine oxidase inhibitor' or have taken any in the last two weeks
- have been given the 200 mg strength and you have not used any opioid medicines before
- have an addiction or history of abuse of alcohol or drugs.

Do not take MS CONTIN tablets if you are allergic to morphine, opioid painkillers, or any of the ingredients listed at the end of this leaflet.

Some of the strengths of this medicine also contain lactose (except for 100 mg and 200 mg) so consider this if you are lactose intolerant.

Do not take this medicine after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work very well.

Do not take it if the packaging is torn or shows signs of tampering.

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

Like most medicines of this kind, MS CONTIN tablets are not recommended to be taken during pregnancy. Your doctor will discuss

the risks and benefits of using it if you are pregnant.

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

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

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 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.

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 breast-feeding or planning to breast-feed.

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

If you have not told your doctor about any of the above, tell them before you start taking MS CONTIN tablets.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a

prescription from your pharmacy, supermarket or health food shop.

Some medicines and MS CONTIN tablets may interfere with each other.

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 MS CONTIN 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 MS CONTIN 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.

These medicines or alcohol may be affected by MS CONTIN tablets, may affect how well MS CONTIN tablets work or may increase side effects. You may need to use different amounts of your medicines, or take different medicines.

Your doctor or pharmacist has more information on medicines to be

careful with or avoid while taking this medicine.

How to take MS CONTIN tablets

How much to take

Your doctor will tell you exactly how much to take.

Follow the instructions your doctor or pharmacist gives you exactly.

How to take it

Swallow MS CONTIN tablets whole. Do not break, chew, crush or dissolve them.

MS CONTIN 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 MS CONTIN 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

Take MS CONTIN tablets every 12 hours.

Take MS CONTIN tablets regularly to control the pain.

Taking them at the same time each day will have the best effect and will mean that the onset of pain is prevented. If, however, you begin to experience pain ('breakthrough pain') and you are taking your MS CONTIN tablets as prescribed, 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.

If you forget to take it

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

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

This will increase the chance of you getting unwanted side effects.

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

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

For example, take your medicine at the same time each morning and evening such as 8 a.m. and 8 p.m.

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 your nearest hospital, if you think that you or anyone else may have taken too many MS CONTIN tablets.

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 experience difficulties in breathing, become drowsy and tired, lack muscle tone, have cold or clammy skin, have constricted pupils,

have very low blood pressure or slow heart rate, and possibly may even become unconscious or 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 it

Things you must do

Take MS CONTIN tablets exactly as your doctor has prescribed.

Before you start on a new medicine, remind your doctor and pharmacist that you are taking MS CONTIN tablets.

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.

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

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

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

Keep enough MS CONTIN tablets with you to last over weekends and holidays.

Things you must not do

Do not take MS CONTIN tablets to treat any other complaint 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, exceed the dose recommended or change 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 have unwanted side effects such as 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

Do not drive or operate machinery until you know how MS CONTIN tablets affect you.

MS CONTIN tablets may cause drowsiness, dizziness or may affect alertness. Discuss these aspects and any impact on your driving or operating machinery with your doctor.

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

You may feel drowsy when you begin to take MS CONTIN 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.

Tell your doctor if you suffer from nausea or vomiting when taking MS CONTIN tablets.

If you vomit after taking your dose, your pain may come back as you may not have absorbed your morphine. If this happens, speak to your doctor. Your doctor may

prescribe some medicine to help you stop vomiting.

Tell your doctor if taking MS CONTIN tablets causes constipation.

Your doctor can advise you about your diet, the proper use of laxatives and suitable exercise you can do to help you manage this.

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

All medicines may have some unwanted side effects. Sometimes they are serious but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking MS CONTIN tablets.

This medicine helps most people with severe pain, but it may have unwanted side effects in a few people. Other side effects not listed here may also occur in some people.

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

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

- mild abdominal problems such as feeling sick, loss of appetite or constipation
- dry mouth or changes in taste
- sweating
- trouble sleeping
- trouble with your balance
- new problems with your eyesight

- skin rash, redness in the face or itching
- irregular periods or sexual problems
- muscle twitching or muscle tightness
- swelling of legs or ankles.

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

- stomach discomfort or cramps, vomiting, indigestion or abdominal pain
- abnormal thinking or changes in mood
- drowsiness, fainting or dizziness especially when standing up
- 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.

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.

- 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.

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.

When seeking medical attention, take this leaflet and any remaining tablets with you to show the doctor.

After taking it

Storage

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

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

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

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

Heat and damp 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 the tablets or the tablets have passed their expiry date, ask your pharmacist how to dispose of medicines no longer required.

Product Description

What it looks like

MS CONTIN® tablets are film-coated and biconvex in shape and are available in seven strengths:

5 mg - white, marked 5 mg on one side

10 mg - light tan, marked 10 mg on one side

15 mg - light green, marked 15 mg on one side

30 mg - purple, marked 30 mg on one side

60 mg - orange, marked 60 mg on one side

100 mg - grey, marked 100 mg on one side

200 mg - teal green, marked 200 mg on one side.

MS CONTIN® tablets are available in boxes containing blister packs of either 20 or 60 tablets.

Ingredients

Active ingredients:

- 5 mg tablets contain 5 mg morphine sulfate
- 10 mg tablets contain 10 mg morphine sulfate
- 15 mg tablets contain 15 mg morphine sulfate
- 30 mg tablets contain 30 mg morphine sulfate
- 60 mg tablets contain 60 mg morphine sulfate
- 100 mg tablets contain 100 mg morphine sulfate
- 200 mg tablets contain 200 mg morphine sulfate.

Inactive ingredients:

- lactose (except 100 and 200 mg)
- hydroxyethyl cellulose
- cetostearyl alcohol
- magnesium stearate
- talc.

All MS CONTIN® tablets are coated with hypromellose, macrogol 400 and E171 (titanium dioxide).

In addition, the tablets also contain the colourants listed below:

10 mg tablet: E172 (iron oxide red, black and yellow)

15 mg tablet: E172 (iron oxide yellow), E104 (quinoline yellow), E132 (indigo carmine) and E133 (brilliant blue FCF)

30 mg tablet: E127 (erythrosine), E132 (indigo carmine) and E110 (sunset yellow FCF)

60 mg tablet: E110 (sunset yellow FCF), E104 (quinoline yellow) and E127 (erythrosine)

100 mg tablet: E172 (iron oxide black and yellow) and E132 (indigo carmine)

200 mg tablet: E104 (quinoline yellow) and E133 (brilliant blue FCF).

This medicine does not contain sucrose, gluten or tartrazine.

Manufacturer / Sponsor

MS CONTIN® tablets are made in the UK and supplied in Australia by:

Mundipharma Pty Limited

ABN 87 081 322 509

50 Bridge Street

SYDNEY NSW 2000

Phone: 1800 188 009

®: MS CONTIN is a Registered Trademark.

This leaflet was updated in March 2010.

Australian Register Numbers for MS CONTIN® tablets:

5 mg: AUST R 51760

10 mg: AUST R 14461

15 mg: AUST R 78208

30 mg: AUST R 43086

60 mg: AUST R 43087

100 mg: AUST R 43088

200 mg: AUST R 78209