

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

[®]MS CONTIN[®]
(Morphine Sulfate Sustained Release Tablets)

Read this carefully before you start taking MS CONTIN and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about MS CONTIN.

Serious Warnings and Precautions

- Even if you take MS CONTIN as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to overdose and death. To understand your risk of opioid addiction, abuse, and misuse you should speak to your prescriber (e.g., doctor).
- Life-threatening breathing problems can happen while taking MS CONTIN, especially if not taken as directed. Babies are at risk of life-threatening breathing problems if their mothers take opioids while pregnant or nursing.
- Never give anyone your MS CONTIN. They could die from taking it. If a person has not been prescribed MS CONTIN, taking even one dose can cause a fatal overdose. This is especially true for children.
- If you took MS CONTIN while you were pregnant, whether for short or long periods of time or in small or large doses, your baby can suffer life-threatening withdrawal symptoms after birth. This can occur in the days after birth and for up to 4 weeks after delivery. If your baby has any of the following symptoms:
 - has changes in their breathing (such as weak, difficult or fast breathing)
 - is unusually difficult to comfort
 - has tremors (shakiness)
 - has increased stools, sneezing, yawning, vomiting, or feverSeek immediate medical help for your baby.
- Taking MS CONTIN with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

What is MS CONTIN used for?

MS CONTIN is used for the long-term management of pain, when:

- the pain is severe enough to require daily, around-the-clock pain medication
- the doctor determines that other treatment options are not able to effectively manage your pain

MS CONTIN is NOT used “as needed” to treat pain that you only have once in a while.

How does MS CONTIN work?

MS CONTIN is an oral sustained release tablet that slowly releases morphine over a 12 hour period. MS CONTIN contains morphine which is a pain medication belonging to the class of medicines known as opioids which includes codeine, fentanyl and oxycodone. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

What are the ingredients in MS CONTIN?

Medicinal ingredients: morphine sulfate

Non-medicinal ingredients: cetostearyl alcohol, hydroxyethyl cellulose, hydroxypropyl methylcellulose, lactose (5, 15, 30, 60 mg only), magnesium stearate, polyethylene glycol, talc and dioxide.

The tablet coatings contain the following additional ingredients:

15 mg: D&C Yellow No. 10 Aluminum Lake, FD&C Blue No. 1 Aluminum Lake, FD&C Blue No. 2 Aluminum Lake

30 mg: D&C Red No. 7 Calcium Lake, FD&C Blue No. 2 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake, Polysorbate 80

60 mg: D&C Yellow No. 10 Aluminum Lake, FD&C Red No. 3 Aluminum Lake, FD&C Yellow No. 6 Aluminum Lake

100 mg: FD&C Blue No. 2 Aluminum Lake, Iron oxide yellow, Iron oxide black

200 mg: FD&C Red No. 3, FD&C Yellow No. 6 Aluminum Lake, Polysorbate 80

MS CONTIN comes in the following dosage forms:

Sustained Release Tablets: 5 mg, 15 mg, 30 mg, 60 mg, 100 mg and 200 mg.

Do not use MS CONTIN if:

- your doctor did not prescribe it for you
- you are allergic to morphine, or any of the other ingredients of MS CONTIN
- you have mild or short term pain that can be controlled by the occasional use of pain medications, including those available without a prescription
- you have severe asthma, trouble breathing or other breathing problems
- you have any heart problems
- you have bowel blockage or narrowing of the stomach or intestines
- you have severe pain in your abdomen
- you have a head injury
- if you are at risk for seizures
- you have a brain tumor
- you suffer from alcoholism
- you are taking or have taken within the past 2 weeks a monoamine oxidase inhibitor (MAO) medication (such as phenelzine sulfate, tranylcypromine sulfate, moclobemide or selegiline)
- you are pregnant or plan to become pregnant, breast-feeding, or in labour
- are going to have, or recently had, a planned surgery

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MS CONTIN. Talk about any health conditions or problems you may have, including if you:

- have a history of illicit or prescription drug or alcohol abuse
- have severe kidney, liver or lung disease
- have heart disease
- have a history of sleep apnea
- have low blood pressure
- have past or current depression
- suffer from chronic or severe constipation
- have problems with your thyroid, adrenal or prostate gland
- have, or had in the past, hallucinations or other severe mental problems
- suffer from migraines
- are planning to become pregnant

Other warnings you should know about:

Opioid dependence and addiction

There are important differences between physical dependence and addiction. It is important that you talk to your doctor if you have questions or concerns about abuse, addiction or physical dependence.

Pregnancy, nursing, labour and delivery

Do not use MS CONTIN while pregnant, nursing, during labour or delivery. Opioids can be transferred to your baby through breast milk, or while still in the womb. MS CONTIN can then cause life-threatening breathing problems in your unborn baby or nursing infant.

If you are pregnant and are taking MS CONTIN, it is important that you don't stop taking your medication all of a sudden. If you do, it can cause a miscarriage or a still-birth. Your doctor will monitor and guide you on how to slowly stop taking MS CONTIN. This may help avoid serious harm to your unborn baby.

Driving and using machines

Before you do tasks which may require special attention, you should wait until you know how you react to MS CONTIN. MS CONTIN can cause:

- drowsiness
- dizziness or
- light headedness

This can usually occur after you take your first dose and when your dose is increased.

Disorder of the adrenal gland

You may develop a disorder of the adrenal gland called adrenal insufficiency. This means that your adrenal gland is not making enough of certain hormones. You may experience symptoms such as:

- nausea, vomiting
- feeling tired, weak or dizzy
- decreased appetite

You may be more likely to have problems with your adrenal gland if you have been taking opioids for longer than one month. Your doctor may do tests, give you another medication, and slowly take you off MS CONTIN.

Serotonin Syndrome

MS CONTIN can cause serotonin syndrome, a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles and digestive system work. You may develop serotonin syndrome if you take MS CONTIN with certain anti-depressants or migraine medications.

Serotonin syndrome symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
- muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination;
- fast heartbeat, changes in blood pressure;
- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma.

Sexual Function/Reproduction

Long term use of opioids may lead to a decrease in sex hormone levels. It may also lead to low libido (desire to have sex), erectile dysfunction or being infertile.

Sleep apnea

Opioids can cause a problem called sleep apnea (stopping breathing from time to time while sleeping). Tell your doctor if you have a history of sleep apnea or if anyone notices that you stop breathing from time to time while sleeping.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with MS CONTIN:

- alcohol, including prescription and non-prescription medications containing alcohol.
Do not drink alcohol while taking MS CONTIN. It can lead to:
 - drowsiness
 - unusually slow or weak breathing
 - serious side effects or
 - a fatal overdose
- other sedative drugs which may enhance the drowsiness caused by MS CONTIN
- other opioid analgesics (for pain)
- general anesthetics (used during surgery)
- drugs used to help you sleep or to reduce anxiety (benzodiazepines)
- antidepressants (for depression and mood disorders). **Do not** take MS CONTIN with monoamine oxidase (MAO) inhibitors or if you have taken MAO inhibitors in the last 14 days before treatment with MS CONTIN
- drugs used to treat serious mental or emotional disorders, such as schizophrenia
- anticonvulsants (used to treat seizures)
- antihistamines (for allergies)
- anti-emetics (for prevention of vomiting)
- drugs used to treat muscle spasms and back pain
- some heart medication (beta blockers)
- anticoagulants (blood thinners)
- drugs used to treat migraines (e.g. triptans)
- St. John's Wort

How to take MS CONTIN:

MS CONTIN tablets are designed to work properly over 12 hours when swallowed whole.

MS CONTIN 100 mg and 200 mg tablets are for use in “opioid tolerant” patients only. Your doctor will tell you when you are “opioid tolerant” to a certain dose of MS CONTIN.

Swallow whole. Do not cut, break, chew, dissolve or crush since this can cause the release of the entire 12-hour dose of morphine, which can seriously harm you. Only the 200 mg tablet is scored and may be broken in half. The half tablet must also be swallowed intact.

MS CONTIN tablets must be taken regularly, every 12 hours (with or without food and with sufficient fluid, e.g., 4 to 6 oz. of water), to treat pain.

Usual Adult Starting Dose:

Dosage is individualized. Be sure to follow your doctor’s dosing instructions exactly. Do not increase or decrease your dose without consulting your doctor. Taking higher doses can lead to more side effects and a greater chance of overdose.

Review your pain regularly with your doctor to determine if you still need MS CONTIN. Be sure to use MS CONTIN only for the condition for which it was prescribed.

Should your pain increase or any other complaint as a result of taking MS CONTIN, tell your doctor immediately.

Stopping your Medication:

If you have been taking MS CONTIN for more than a few days you should not stop taking it all of a sudden. Your doctor will monitor and guide you on how to slowly stop taking MS CONTIN. You should do it slowly to avoid uncomfortable symptoms such as having:

- body aches
- diarrhea
- goosebumps
- loss of appetite
- nausea
- feeling nervous or restless
- runny nose
- sneezing
- tremors or shivering
- stomach cramps
- rapid heart rate (tachycardia)
- having trouble sleeping
- an unusual increase in sweating
- heart palpitations
- an unexplained fever
- weakness
- yawning

By reducing or stopping your opioid treatment, your body will become less used to opioids. If you start treatment again, you will need to start at the lowest dose. You may overdose if you restart at the last dose you took before you slowly stopped taking MS CONTIN.

Refilling Prescriptions for MS CONTIN:

A new written prescription is required from your doctor each time you need more MS CONTIN. Therefore, it is important that you contact your doctor before your current supply runs out.

Only obtain prescriptions for this medicine from the doctor in charge of your treatment. Do not seek prescriptions from other doctors unless you switch to another doctor for your pain management.

Overdose:

If you think you have taken too much MS CONTIN, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Signs of overdose may include:

- abnormally slow or weak breathing
- dizziness
- confusion
- extreme drowsiness

Missed Dose:

It is important that you do not miss any doses. If you miss a dose, take your next dose at your usual time. You should always try to get back on track with your regular dosing schedule (e.g., 8 o'clock in the morning and 8 o'clock in the evening). If you miss several doses in a row, talk to your doctor before restarting your medication.

What are possible side effects from using MS CONTIN?

These are not all the possible side effects you may feel when taking MS CONTIN. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- drowsiness
- insomnia
- dizziness
- fainting
- nausea, vomiting, or a poor appetite
- dry mouth
- headache
- problems with vision
- weakness, uncoordinated muscle movement
- itching
- sweating
- constipation
- low sex drive, impotence (erectile dysfunction), infertility

Talk with your doctor or pharmacist about ways to prevent constipation when you start using MS CONTIN.

If nausea and vomiting become troublesome during prolonged therapy with MS CONTIN, talk to your doctor or pharmacist.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE Overdose: hallucinations, confusion, inability to walk normally, slow or weak breathing, extreme sleepiness, sedation, or dizziness, floppy muscles/low muscle tone cold and clammy skin.			✓
Respiratory Depression: Slow, shallow or weak breathing.			✓
Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
Bowel Blockage (impaction): abdominal pain, severe constipation, nausea			✓
Withdrawal: nausea, vomiting, diarrhea, anxiety, shivering, cold and clammy skin, body aches, loss of appetite, sweating.		✓	
Fast, Slow or Irregular Heartbeat: heart palpitations.		✓	
Low Blood Pressure: dizziness, fainting, light-headedness.	✓		
Serotonin Syndrome: agitation or restlessness, loss of muscle control or muscle twitching, tremor, diarrhea			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/drug.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- **Keep unused or expired MS CONTIN in a secure place to prevent theft, misuse or accidental exposure.**
- Store at room temperature (15° - 30°C). Keep in a dry place.
- **Keep MS CONTIN under lock, out of sight and reach of children and pets.**
- **Never take medicine in front of small children as they will want to copy you. Accidental ingestion by a child is dangerous and may result in death. If a child accidentally takes MS CONTIN, get emergency help right away.**

Disposal:

MS CONTIN should never be thrown into household trash, where children and pets may find it. It should be returned to a pharmacy for proper disposal.

If you want more information about MS CONTIN:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.purdue.ca, or by calling 1-800-387-4501.

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