

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

^NMS 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. This can lead to overdose and death. To understand your risk of opioid addiction, abuse, and misuse you should speak to your healthcare professional.
- When you take MS CONTIN it must be swallowed whole. Do not break, crush, chew, or dissolve the tablet. This can be dangerous and can lead to death or seriously harm you. Only the 200 mg tablet is scored and may be broken in half. The half tablet must also be swallowed intact.
- 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 fever.

Seek 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 in adults and children (less than 18 years of age) to manage long-term pain, when:

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

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

How does MS CONTIN work?

MS CONTIN is a painkiller belonging to the class of medicines known as opioids. 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 (15, 30, 60 mg only), magnesium stearate, polyethylene glycol, talc, and titanium 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 black, Iron oxide yellow
- 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: 15 mg, 30 mg, 60 mg, 100 mg and 200 mg of morphine sulfate.

Do not use MS CONTIN if:

- your healthcare professional 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 painkillers, including those available without a prescription.
- you have severe asthma, trouble breathing, or other lung problems.
- you have any heart problems.
- you have bowel blockage or narrowing of the stomach or intestines.
- You have a condition where the bowel does not work properly (ileus).
- you have severe pain in your abdomen (for example, from appendicitis or pancreatitis).
- you have increased pressure in your skull, have a head injury, or a brain tumour.
- you have severe CNS depression (nervous system slows down).
- you have or have a history with epilepsy.
- you suffer from alcoholism or alcohol withdrawal.
- you are taking or have taken within the past 2 weeks a monoamine oxidase inhibitor (MAOI) (such

as phenelzine sulfate, tranylcypromine sulfate, moclobemide, or selegiline).

- you are pregnant or plan to become pregnant or are in labour and delivery.
- you are breast-feeding.
- you are going to have a surgery or operation or have had a surgery in the last 24 hours.

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 kidney or liver problems.
- have sickle cell disease.
- have been told you are at risk of having heart problems or seizures.
- have a sleep disorder which causes pauses in breathing or shallow breathing while sleeping (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 have had problems with your mood (such as depression or anxiety), hallucinations, or other mental health problems.
- have gastrointestinal (GI) problems.
- have a history of pancreas or gall bladder problems.
- are planning to breastfeed.
- have difficulty urinating.
- are over 50 years of age.
- have a condition that causes weakness or frailty.
- have circulatory problems (e.g., body does not get enough oxygen and nutrients to function properly due to lack of blood flow).
- are planning on drinking alcohol. Drinking alcohol while taking MS CONTIN may cause dangerous side effects, including death. Do not drink alcohol while taking MS CONTIN.
- take hypnotics, centrally acting analgesics, opioids, or psychotropic medicines. Ask your healthcare professional if you are unsure.

Other warnings you should know about:

Taking MS CONTIN can cause the following serious side effects:

- **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 healthcare professional may do tests, give you another medication, and slowly take you off MS CONTIN.

- **Serotonin toxicity (also known as serotonin syndrome):** MS CONTIN can cause serotonin toxicity, 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 toxicity if you take MS CONTIN with certain anti-depressants or migraine medications. Serotonin toxicity 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.
- **Sleep apnea:** Opioids can cause a problem called sleep apnea (stopping breathing from time to time while sleeping). Tell your healthcare professional if you have a history of sleep apnea or if anyone notices that you stop breathing from time to time while sleeping.

See the **Serious side effects and what to do about them** table for more information on these and other serious side effects.

Opioid dependence and addiction: Like any opioid, MS CONTIN may cause mental and physical dependence. Morphine sulfate also has the potential to cause addiction. There are important differences between physical dependence and addiction. Tolerance means that, over time, a higher dose may be needed to get the same level of pain relief. It is important that you talk to your healthcare professional if you have questions or concerns about addiction, physical dependence, or tolerance. Your healthcare professional should prescribe and administer MS CONTIN with the same degree of caution appropriate to the use of other oral opioid medications. It is not recommended to use these products for a long period of time.

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 healthcare professional 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.

Sexual Function and 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.

Worsening Pain: Taking opioids for pain can sometimes have the unintended effect of making your pain feel worse (opioid-induced hyperalgesia) even though your opioid dose has been unchanged or increased. This can also include feeling pain in new places in your body, or feeling pain from something that would not normally hurt, for example, feeling pain from clothing touching your skin. Tell your healthcare professional if you notice a change like this in your pain while you are taking MS CONTIN.

Testing and check-ups: Your healthcare professional will regularly monitor your health. This includes monitoring for signs of:

- misuse and abuse;
- sleep apnea (a sleep disorder which causes pauses in breathing or shallow breathing while sleeping);
- respiratory depression and sedation (e.g., slow, shallow, or weak breathing).

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

Serious Drug Interactions

Serious drug interactions with MS CONTIN include:

- benzodiazepines used to help you sleep or that help reduce anxiety.
- central nervous system (CNS) depressants used to slow down the nervous system. These can include:
 - other opioids and mixed opioid agonists/antagonists used to relieve pain (e.g., methadone, pentazocine, nalbuphine, butorphanol, buprenorphine);
 - hypnotics used to help with sleeping;
 - antidepressants used for depression and mood disorders (e.g., fluoxetine, citalopram, venlafaxine; tricyclic antidepressants such as amitriptyline, imipramine, maprotiline, paroxetine; serotonin norepinephrine re-uptake inhibitors [SNRIs]; and selective serotonin re-uptake inhibitors [SSRIs] such as St. John's Wort);
 - anxiolytics, tranquilizers, and phenothiazines used to treat mental or emotional disorders;
 - muscle relaxants used to treat muscle spasms and back pain (e.g., baclofen);
 - general anaesthetics used during surgery;
 - antipsychotics and neuroleptics used to treat mental health disorders (e.g., chlorpromazine, pimozide, haloperidol, droperidol, ziprasidone, and risperidone);
 - antihistamines used to treat allergies;
 - antiemetics used to prevent nausea or vomiting (e.g., domperidone, granisetron, dolasetron, and ondansetron);
 - sedatives which may enhance the drowsiness;
 - pregabalin, used to treat nerve pain;
 - gabapentin, used to prevent and control seizures in the treatment of epilepsy;
 - beta blockers used to lower blood pressure;
 - alcohol. This includes prescription and non-prescription medications that contain alcohol. Do not drink alcohol while you are taking MS CONTIN. It can lead to drowsiness, usually slow or weak breathing, serious side effects, or a fatal overdose.
- monoamine oxidase inhibitors (MAOIs) used to treat depression. Do not take MS CONTIN with MAOIs or if you have taken MAOIs in the last 14 days.

The following may also interact with MS CONTIN:

- anticoagulants, used to thin the blood and prevent blood clots (e.g., warfarin and other coumarins)
- drugs used to treat migraines (e.g., triptans)

If you are unsure about the medications you are taking, ask your healthcare professional.

How to take MS CONTIN:

- MS CONTIN must be taken orally, by mouth. Do **NOT** administer the MS CONTIN tablets via any

other route as this can cause serious harm, including death.

- Take MS CONTIN every 12 hours as prescribed, with a glass of water. It can be taken with or without food.
- **Swallow the whole tablet. Do not cut, break, chew, dissolve or crush MS CONTIN tablets. This can be dangerous and can lead to death or seriously harm you. Only the 200 mg tablet is scored and may be broken in half. The half tablet must also be swallowed intact.**
- The MS CONTIN 100 mg and 200 mg strength tablets will only be prescribed if you are “opioid tolerant”. Your healthcare professional will tell you when you are “opioid tolerant” to a certain dose of MS CONTIN.
- Review your pain regularly with your healthcare professional to determine if you still need MS CONTIN. Be sure to use MS CONTIN only for the condition for which it was prescribed.

Usual dose:

Your dose is tailored/personalized just for you. Take it exactly as your healthcare professional has told you to. Do not increase or decrease your dose without consulting your healthcare professional. Taking higher doses can lead to more side effects and a greater chance of overdose.

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 healthcare professional 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 healthcare professional each time you need more MS CONTIN. Therefore, it is important that you contact your healthcare professional before your current supply runs out.

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

Overdose:

Signs of overdose with MS CONTIN may include:

- abnormally slow or weak breathing
- dizziness
- confusion
- extreme drowsiness
- shrinking or widening of the pupils
- floppy muscles/low muscle tone
- cold and clammy skin
- slow heart rate
- low blood pressure
- muscle weakness, cramping, or aching
- toxic leukoencephalopathy (a brain disorder affecting the brain's white matter)
- sleep apnea (a sleep disorder which causes pauses in breathing or shallow breathing while sleeping)
- cardiac arrest (heart stops beating suddenly)

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

Missed Dose:

It is important that you do not miss any doses. If you miss:

- **One dose:** Skip the missed dose and take your next dose as scheduled. Do not take two doses at once to make-up for a missed dose.
- **Several doses in a row:** Talk to your healthcare professional before restarting your medication.

What are possible side effects from using MS CONTIN?

These are not all the possible side effects you may have when taking MS CONTIN. If you experience any side effects not listed here, tell 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. Talk with your healthcare professional about ways to prevent constipation when you start taking MS CONTIN.
- low sex drive, impotence (erectile dysfunction), infertility

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	
UNCOMMON			
Hallucinations: seeing or hearing things that are not there.			✓
Seizures (fits): uncontrollable shaking with or without loss of consciousness.			✓
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.		✓	
Hypotension (low blood pressure): dizziness, fainting, light-headedness.	✓		
Serotonin toxicity (also known as serotonin syndrome): a reaction which may cause feelings of agitation or restlessness, flushing, muscle twitching, involuntary eye movements, heavy sweating, high body temperature (>38°C), or rigid muscles.			✓

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	
UNKNOWN FREQUENCY			
Disorder of the adrenal gland: nausea, vomiting, anorexia, fatigue, weakness, dizziness, or low blood pressure.			✓
Sleep apnea: stop breathing for short periods during your normal nightly sleep.		✓	

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

- Store at room temperature (15° - 30°C). Keep in a dry place.
- Keep unused or expired MS CONTIN in a secure place to prevent theft, misuse, or accidental exposure.
- 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.
- 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.

This leaflet was prepared by Purdue Pharma.

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