

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

**<sup>N</sup>MS•IR<sup>®</sup>**

**(Morphine Sulfate Immediate Release Tablets)**

Read this carefully before you start taking MS•IR 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•IR.

#### **Serious Warnings and Precautions**

- Even if you take MS•IR 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 prescriber (e.g., healthcare professional).
- When you take MS•IR tablets they must be swallowed whole. Do not cut, break, crush, chew, or dissolve the tablet. This can be dangerous and can lead to death or seriously harm you.
- Life-threatening breathing problems can happen while taking MS•IR, 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•IR. They could die from taking it. If a person has not been prescribed MS•IR, taking even one dose can cause a fatal overdose. This is especially true for children.
- If you took MS•IR 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•IR 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•IR used for?**

MS•IR is a medicine used to manage your pain

#### **How does MS•IR work?**

MS•IR is a painkiller belonging to the class of medicine known as opioids. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

#### **What are the ingredients in MS•IR?**

Medicinal ingredient: morphine sulfate

Non-medicinal ingredients: croscarmellose sodium, hydroxypropyl methylcellulose, lactose, magnesium stearate, microcrystalline cellulose and polyethylene glycol 400.

**MS•IR comes in the following dosage forms:**

Immediate Release Tablets: 5 mg, 10 mg, 20 mg and 30 mg.

**Do not use MS•IR if:**

- your healthcare professional did not prescribe it for you
- you are allergic to morphine, or any of the other ingredients in MS•IR
- you can control your pain by the occasional use of other pain medications. This includes 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 (for example, from appendicitis or pancreatitis)
- you have increased pressure in your skull, have a head injury or a brain tumour.
- you have or have had a history of 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 going to have a surgery or operation, or have had a surgery in the last 24 hours
- you are pregnant or planning to become pregnant or you are in labour or delivery
- you are breastfeeding

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MS•IR. 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 a sleep disorder which causes pauses in breathing or shallow breathing while sleeping (sleep apnea).
- have low blood pressure.
- have or have had problems with your mood (such as depression or anxiety), hallucinations, or other mental health problems.
- suffer from chronic or severe constipation.
- have a history of pancreas or gall bladder problems.
- have problems with your thyroid, adrenal or prostate gland.
- 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•IR may cause dangerous side effects, including death. Do not drink alcohol while taking MS•IR.
- take hypnotics, centrally acting analgesics, opioids, or psychotropic medicines. Ask your healthcare professional if you are unsure.

**Other warnings you should know about:**

***Opioid dependence and addiction***

Like any opioid, MS•IR may cause mental and physical dependence. Morphine sulfate also has

the potential to cause addiction even at regular doses. 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•IR 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•IR while pregnant, nursing, during labour or delivery. Opioids can be transferred to your baby through breast milk, or while still in the womb. MS•IR can then cause life-threatening breathing problems in your unborn baby or nursing infant.

If you are pregnant and are taking MS•IR, 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•IR. 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•IR. MS•IR 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 healthcare professional may do tests, give you another medication, and slowly take you off MS•IR.

***Serotonin toxicity (also known as serotonin syndrome):*** MS•IR 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•IR 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 healthcare professional if you have a history of sleep apnea or if anyone notices that you stop breathing from time to time while sleeping.

### **Worsened 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 doctor if you notice a change like this in your pain while you are taking MS•IR.

**Testing and check-ups:** Your healthcare professional will regularly monitor you for signs of misuse and abuse.

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

**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•IR 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 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•IR. 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•IR with MAOIs or if you have taken MAOIs in the last 14 days.

**The following may also interact with MS•IR:**

- anticonvulsants (used to treat seizures)
- anticoagulants, used to thin the blood and prevent blood clots (e.g., warfarin and other coumatins)
- 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•IR:**

Take MS•IR tablets:

- regularly, usually every 4 to 6 hours, as directed by your healthcare professional
- with a full glass of water
- should not be used longer than necessary

**Swallow whole. Do not cut, break, crush, chew or dissolve the tablet. This can be dangerous and can lead to death or seriously harm you.**

**Usual dose:** Your dose is tailored/personalized just for you. Be sure to follow your healthcare professional's dosing instructions exactly. Do not increase or decrease your dose without consulting your healthcare professional.

Your healthcare professional will prescribe the lowest dose that works to control your pain. It is recommended that you only take MS•IR for up to 7 days. If you need to take MS•IR for longer, your healthcare professional will determine the best dose for you to lower the risk of side effects and overdose. Higher doses can lead to more side effects and a greater chance of overdose.

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

If your pain increases or you develop any side effect as a result of taking MS•IR, tell your healthcare professional immediately.

**Stopping your Medication**

If you have been taking MS•IR 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•IR. 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•IR.

### **Refilling your Prescription for MS•IR:**

A new written prescription is required from your healthcare professional each time you need more MS•IR. Therefore, it is important that you contact your healthcare professional 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 healthcare professional for your pain management.

### **Overdose:**

If you think you, or a person you are caring for, have taken too much MS•IR, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no symptoms.

Signs of overdose may include:

- unusually slow or weak breathing
- dizziness
- confusion
- extreme drowsiness
- muscle weakness, cramping, or aching
- shrinking or widening of the pupils
- lack of muscle shape and tone
- cold and clammy skin
- slow heart rate
- low blood pressure
- toxic leukoencephalopathy (a brain disorder affecting the brain's white matter)

### **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•IR?**

These are not all the possible side effects you may feel when taking MS•IR. 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
- rash
- sweating
- constipation
- low sex drive, impotence (erectile dysfunction), infertility
- severe pain in your abdomen that comes and goes [eg. spasm of the sphincter of Oddi (muscle that controls the flow of bile and pancreatic fluid into the intestine)].

Talk with your healthcare professional or pharmacist about ways to prevent constipation when you start using MS•IR.

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>UNCOMMON</b>			
<b>Seizures</b> (fits): uncontrollable shaking with or without loss of consciousness.			✓
<b>Hallucinations:</b> seeing or hearing things that are not there.			✓
<b>RARE</b>			
<b>Overdose:</b> hallucinations, confusion, inability to walk normally, slow or weak breathing, extreme sleepiness, sedation, or dizziness, floppy muscles/low muscle tone, cold and clammy skin.			✓
<b>Respiratory Depression:</b> slow, shallow or weak breathing.			✓
<b>Allergic Reaction:</b> rash, hives, swelling of the face, lips, tongue			✓

or throat, difficulty swallowing or breathing			
<b>Bowel Blockage (impaction):</b> abdominal pain, severe constipation, nausea.			✓
<b>Withdrawal:</b> nausea, vomiting, diarrhea, anxiety, shivering, cold and clammy skin, body aches, loss of appetite, sweating.		✓	
<b>Fast, Slow or Irregular Heartbeat:</b> heart palpitations.		✓	
<b>Hypotension</b> (Low Blood Pressure): dizziness, fainting, light-headedness.	✓		
<b>Serotonin toxicity</b> (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.			✓
<b>UNKNOWN</b>			
<b>Disorder of the adrenal gland:</b> nausea, vomiting, anorexia, fatigue, weakness, dizziness, or low blood pressure.			✓
<b>Sleep apnea:</b> stop breathing for short periods during your normal nightly sleep.		✓	
<b>Severe Cutaneous Adverse Reactions (SCAR) (severe skin reactions that may also affect other organs):</b> Skin peeling, scaling, or blistering (with or without pus) which may also affect your eyes, mouth, nose or genitals, itching, severe rash, bumps under the skin, skin pain, skin color changes (redness, yellowing, purplish). Swelling and redness of eyes or face. Flu-like feeling, fever, chills, body aches, swollen glands, cough. Shortness of breath, chest pain			✓



or discomfort.			
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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 ([canada.ca/drug-device-reporting](https://canada.ca/drug-device-reporting)) 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•IR in a secure place to prevent theft, misuse or accidental exposure.**
- Store tablets at room temperature (15° - 30°C). Keep in a dry place.
- **Keep MS•IR 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•IR, get emergency help right away.**

### Disposal:

**MS•IR 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•IR:

- 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://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website [www.purdue.ca](http://www.purdue.ca), or by calling 1-800-387-4501.

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