

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Sandoz Morphine SR

Morphine sulfate sustained release tablets

Read this carefully before you start taking Sandoz Morphine SR tablets 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 Sandoz Morphine SR.

Serious Warnings and Precautions

- **Even if you take Sandoz Morphine SR 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 Sandoz Morphine SR, 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 Sandoz Morphine SR. They could die from taking it. If a person has not been prescribed Sandoz Morphine SR, taking even one dose can cause a fatal overdose. This is especially true for children.**
- **If you took Sandoz Morphine SR 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. 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 breathing changes (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 Sandoz Morphine SR 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 Sandoz Morphine SR used for?

Sandoz Morphine SR 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

Sandoz Morphine SR is NOT used (“as needed”) to treat pain that you only have once in a while.

How does Sandoz Morphine SR work?

Sandoz Morphine SR is an oral sustained release tablet that slowly releases morphine over a 12 hour period. Sandoz Morphine SR 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 Sandoz Morphine SR?

Medicinal ingredient: morphine sulfate

Non-medicinal ingredients: hypromellose, lactose anhydrous, magnesium stearate, polyethylene glycol, polyvinyl alcohol, stearic acid, talc and titanium dioxide.

15 mg:	FD&C blue #1 brilliant blue FCF aluminum lake FD&C yellow #5 tartrazine aluminum lake
30 mg:	D&C red #7 lithol rubin B calcium lake FD&C blue #1 brilliant blue FCF aluminum lake
60 mg:	FD&C yellow #6 sunset yellow FCF aluminum lake
100 mg:	FD&C Blue #2/ Indigo Carmine AL 3%-5% Ferrosferric oxide/black iron oxide Iron Oxide Yellow
200 mg:	Erythrosine Aluminum Lake FD&C Blue #2/ Indigo Carmine Aluminum Lake FD&C Yellow #6/ Sunset Yellow FCF Aluminum Lake

Sandoz Morphine SR comes in the following dosage forms:

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

Do not use Sandoz Morphine SR if:

- your doctor did not prescribe it for you
- you are allergic to morphine, other opioids, or any of the other ingredients of Sandoz Morphine SR

- 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 lung problems
- you have a condition where the small bowel does not work properly (paralytic ileus) or you have severe pain in your abdomen
- you have a head injury
- if you are at risk for seizures
- you suffer from alcoholism
- you are taking, or have taken within the past 2 weeks, a monoamine oxidase inhibitor medication (e.g., phenelzine sulphate, tranylcypromine sulphate, 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 Sandoz Morphine SR. 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 disease or lung disease
- have heart disease
- have low blood pressure
- have problems with your thyroid, adrenal or prostate gland
- have past or current depression
- suffer from chronic or severe constipation
- have, or had in the past, hallucinations or other severe mental problems
- suffer from migraines

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 Sandoz Morphine SR while pregnant, nursing, during labour or delivery. Opioids can be transferred to your baby through breast milk, or while still in the womb. Sandoz Morphine SR can then cause life-threatening breathing problems in your unborn baby or nursing infant.

Driving and using machines: Before you perform tasks which may require special attention, you should wait until you know how you react to Sandoz Morphine SR. Sandoz Morphine SR 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 Sandoz Morphine SR.

Serotonin syndrome: Sandoz Morphine SR 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 Sandoz Morphine SR with certain antidepressants 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.

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 Sandoz Morphine SR:

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

How to take Sandoz Morphine SR:

Sandoz Morphine SR tablets are designed to work properly over 12 hours when swallowed whole.

Sandoz Morphine SR 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 Sandoz Morphine SR.

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.

Sandoz Morphine SR 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 Sandoz Morphine SR. Be sure to use Sandoz Morphine SR only for the condition for which it was prescribed.

Should your pain increase or any other complaint as a result of taking Sandoz Morphine SR, tell your doctor immediately.

Stopping your Medication:

You should not stop taking Sandoz Morphine SR all at once if you have been taking it for more than a few days.

Your doctor will monitor and guide you on how to slowly stop taking Sandoz Morphine SR. 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 with 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 Sandoz Morphine SR.

Refilling Prescriptions for Sandoz Morphine SR:

A new written prescription is required from your doctor each time you need more Sandoz Morphine SR. 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 Sandoz Morphine SR, 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 Sandoz Morphine SR?

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

Side effects may include:

- Constipation
- Dizziness
- Drowsiness
- Dry mouth
- Headache

- Itching
- Lack of muscle strength
- Nausea and/or vomiting
- Sweating
- Low sex drive, impotence (erectile dysfunction), infertility

Talk with your doctor or pharmacist about ways to prevent constipation when you start using Sandoz Morphine SR.

If nausea and vomiting become troublesome during prolonged therapy with Sandoz Morphine SR, 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

We encourage you to report serious or unexpected side effects to Health Canada. The information is used to check for new safety concerns about health products. As a consumer, your report contributes to the safe use of health products for everyone.

3 ways to report:

- Online at MedEffect: <https://www.canada.ca/en/health-canada/services/drugs-healthproducts/medeffect-canada.html>
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program
Health Canada, Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<https://www.canada.ca/en/health-canada/services/drugs-healthproducts/medeffect-canada.html>).

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 Sandoz Morphine SR in a secure place to prevent theft, misuse or accidental exposure.

Keep Sandoz Morphine SR in a cool, dry place, between 15 and 30°C. Protect from light. Protected from moisture.

Keep Sandoz Morphine SR 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 Sandoz Morphine SR, get emergency help right away.

Disposal:

Sandoz Morphine SR 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 Sandoz Morphine SR:

- 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/drugproducts/drug-product-database.html>); the manufacturer's website <http://www.sandoz.ca>, or by calling 1-800-361-3062.

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