

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

KADIAN[®]
Morphine Sulphate Sustained Release Capsules, Mfr. Std.
10 mg, 20 mg, 50 mg, 100 mg

Read this carefully before you start taking **KADIAN[®]** 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 **KADIAN[®]**.

Serious Warnings and Precautions

- **Even if you take KADIAN[®] 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 KADIAN[®], 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 KADIAN[®]. They could die from taking it. If a person has not been prescribed KADIAN[®], taking even one dose can cause a fatal overdose. This is especially true for children.**
- **If you took KADIAN[®] 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 KADIAN[®] 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 KADIAN[®] used for?

KADIAN[®] is used for the long-term management of pain, when:

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

KADIAN[®] is NOT used (“as needed”) to treat pain that you only have once in a while.

How does KADIAN® work?

KADIAN® is an oral sustained release capsule that slowly releases morphine sulphate over a 24-hour period.

KADIAN® contains morphine sulphate which is a pain medication belonging to the class of medicines known as opioids which also 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 KADIAN®?

Medicinal ingredients: morphine sulphate pentahydrate

Non-medicinal ingredients: Diethyl Phthalate, Ethylcellulose N-50, Gelatin, Hypromellose, Methacrylic Acid Copolymer (Type C), Polyethylene Glycol 6000 (Macrogol 6000), Purified Talc, Sugar Spheres (16-18 mesh), and a black ink containing: ammonium hydroxide, the colouring agent E172 (black iron oxide), potassium hydroxide, propylene glycol, and shellac.

KADIAN® comes in the following dosage forms:

Capsules containing 10 mg, 20 mg, 50 mg or 100 mg morphine sulphate pentahydrate.

The 10 mg capsules are marked "K10" with one black band, the 20 mg capsules are marked "K20" with two black bands, the 50 mg capsules are marked "K50" with three black bands and the 100 mg capsules are marked "K100" with four black bands.

Do not use KADIAN® if:

- your doctor did not prescribe it for you
- you are allergic to morphine sulphate pentahydrate, other opioids, or any of the other ingredients of KADIAN®. You are reminded that KADIAN® contains sucrose and propylene glycol.
- you have mild or short-term pain that can be controlled by the occasional use of pain medication, including those available without a prescription.
- you have severe asthma, trouble breathing, or other 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 gallbladder disease, bile duct disease or problems with your pancreas.
- you have a head injury
- you are at risk for seizures.
- you suffer from alcoholism.
- you have an irregular heartbeat.
- 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.
- you are under 18 years of age.
- you 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 KADIAN®. 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, lung disease.
- have heart disease.

- 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 inflammatory bowel disease or gallbladder disease.
- have problems with your pancreas.
- are going to have, or recently had, a planned surgery.
- 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 KADIAN® while pregnant, nursing, during labour or delivery. Opioids can be transferred to your baby through breast milk, or while still in the womb. KADIAN® can then cause life-threatening breathing problems in your unborn baby or nursing infant.

Driving and using machines: Before you do tasks which may require special attention, you should wait until you know how you react to KADIAN®. KADIAN® 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 KADIAN®.

Serotonin Syndrome: KADIAN® 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 KADIAN® 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.

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 KADIAN®:

- alcohol, including prescription and non-prescription medications containing alcohol. Do not drink alcohol while taking KADIAN®. 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 KADIAN®.
- 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 KADIAN® with monoamine oxidase (MAO) inhibitors or if you have taken MAO inhibitors in the last 14 days before treatment with KADIAN®.
- psychiatric medications (such as amoxapine, maprotiline, nefazodone, trazodone, buspirone, vilazodone, mirtazapine and lithium).
- migraine medicines (5-HT₁ agonists also called triptans).
- serotonergic medications (medicines that change the effect of serotonin in the body), such as dextromethorphan, linezolid, cyclobenzaprine, methylene blue, St. John's Wort and tryptophan.
- drugs used to treat serious mental or emotional disorders such as schizophrenia.
- antihistamines (for allergies).
- anti-emetics (for prevention of vomiting) such as ondansetron, granisetron, dolasetron, palonosetron.
- drugs used to treat muscle spasms and back pain.
- warfarin and other coumarin anticoagulants (for prevention/treatment of blood clots).
- anti-retroviral, anti-fungal and antibiotic drugs.
- diuretics (water tablets).
- cimetidine (remedy for excess stomach acid).
- some heart medication (beta blockers).
- St. John's Wort.

How to take KADIAN®:

Take KADIAN®

- exactly as prescribed
- generally every 24 hours unless otherwise instructed by your doctor

KADIAN® can be swallowed whole or sprinkled on applesauce or custard.

Swallowed:

- swallow the capsule whole
- take the capsule with a full glass of water
- do not cut, break, chew, dissolve or crush the capsule - this can be dangerous and life threatening

Sprinkled:

- measure a tablespoon of warm or cold (4° - 40°C) applesauce or room temperature custard
- open the capsule
- sprinkle contents onto the tablespoon
- ensure the capsule is emptied of all contents
- take the entire tablespoon as soon as possible
- do not chew the contents (beads)
- rinse your mouth and swallow the water
- do not keep any of the food/medicine mixture for another dose

If you do not remember when you sprinkled the medicine on the applesauce or custard, or which food you sprinkled the medicine on, throw out the food/medicine mixture.

Do not take a single dose greater than 20 mg of KADIAN® every 24 hours unless you are “opioid tolerant”. Your doctor will tell you when you are “opioid tolerant” to a certain dose of KADIAN®.

KADIAN® is not recommended for rectal administration.

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 KADIAN®. Be sure to use KADIAN® only for the condition for which it was prescribed.

Should your pain increase or any other complaint develop as a result of taking KADIAN®, tell your doctor immediately.

Stopping your Medication:

You should not stop taking KADIAN® 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 KADIAN®. 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 KADIAN®.

Refilling Prescriptions for KADIAN®:

A new written prescription is required from your doctor each time you need more KADIAN®. 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 KADIAN®, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Signs of overdose may include:

- unusually 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 (for example, 8 o'clock in the morning or 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 KADIAN®?

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

Side effects may include:

- Confusion
- Constipation
- Dizziness
- Drowsiness
- Light-headedness
- Insomnia
- Nausea, vomiting, poor appetite, dry mouth
- Headache
- Problems with vision
- Weakness (lack of muscle strength), uncoordinated muscle movement

- Itching
- Sweating
- Difficulty in urinating
- Low sex drive, impotence (erectile dysfunction), infertility.

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

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-health-products/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 1908C
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-health-products/medeffect-canada.html>).

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

Storage:

- **Keep unused or expired KADIAN® in a secure place to prevent theft, misuse or accidental exposure.**
- Store at room temperature (15° - 25°C). Keep in a dry place.
- **Keep KADIAN® 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 KADIAN®, get emergency help right away.**

Disposal:

KADIAN® 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 KADIAN®:

- 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.mylan.ca), or by calling 1-844-596-9526.

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