

Medication Guide

AVINZA® (ah-ven-zah)

(morphine sulfate extended-release) Capsules, CII

AVINZA is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to treat moderate to severe around-the-clock pain.

Important information about AVINZA:

- Get emergency help right away if you take too much AVINZA (overdose). AVINZA overdose can cause life threatening breathing problems that can lead to death.
- Never give anyone else your AVINZA. They could die from taking it. Store AVINZA away from children and in a safe place to prevent stealing or abuse. Selling or giving away AVINZA is against the law.

Do not take AVINZA if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or have narrowing of the stomach or intestines.

Before taking AVINZA, tell your healthcare provider if you have a history of:

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** AVINZA may harm your unborn baby.
- **breastfeeding.** AVINZA passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements.

When taking AVINZA:

- Do not change your dose. Take AVINZA exactly as prescribed by your healthcare provider.
- Take 1 dose once a day at the same time every day. Do not take more than 1 dose in 24 hours. If you miss a dose, do not take AVINZA. Take your next dose at your usual time the next day.
- Swallow AVINZA whole. Do not cut, break, chew, crush, dissolve, or inject AVINZA.
- If you cannot swallow AVINZA capsules, see the detailed Instructions for Use.
- **Call your healthcare provider if the dose you are taking does not control your pain.**
- **Do not stop taking AVINZA without talking to your healthcare provider.**
- After you stop taking AVINZA, flush any unused capsules down the toilet.

While taking AVINZA Do Not:

- Drive or operate heavy machinery, until you know how AVINZA affects you. AVINZA can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

The possible side effects of AVINZA are:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue or throat, extreme drowsiness, or you are feeling faint.

These are not all the possible side effects of AVINZA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. **For more information go to dailymed.nlm.nih.gov**

Manufactured for: King Pharmaceuticals, Inc., Bristol, TN 37620 by: Alkermes Pharma Ireland Limited", Athlone, Ireland, www.avinza.com or call 1-800-438-1985

Instructions For Use
AVINZA[®] (ah-ven-zah)
(morphine sulfate extended-release) Capsules, CII

- If you cannot swallow AVINZA[®] capsules, tell your healthcare provider. There may be another way to take AVINZA[®] that may be right for you. If your doctor tells you that you can take AVINZA[®] using this other way, follow these steps:

AVINZA[®] can be opened and the pellets inside the capsule can be sprinkled over apple sauce, as follows:

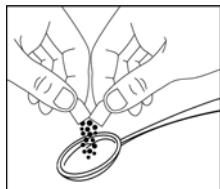


Figure 1

- Open the AVINZA[®] capsule and sprinkle the pellets over approximately one tablespoon of apple sauce (Figure 1).



Figure 2

- Swallow all of the apple sauce and pellets right away. Do not save any of the apple sauce and pellets for another dose (Figure 2).



Figure 3

- Rinse your mouth to make sure you have swallowed all of the pellets. Do not chew the pellets (Figure 3).



Figure 4

- Flush the empty capsule down the toilet right away (Figure 4).

You should not receive AVINZA[®] through a nasogastric tube or gastric tube (stomach tube).