

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 manage pain severe enough to require daily around-the-clock, long-term treatment with an opioid, when other pain treatments such as non-opioid pain medicines or immediate-release opioid medicines do not treat your pain well enough or you cannot tolerate them. • A long-acting (extended-release) opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death. • Not for use to treat pain that is not around-the-clock.
Important information about AVINZA: • Get emergency help right away if you take too much AVINZA (overdose). When you first start taking AVINZA, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur. • Never give anyone 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. Prolonged use of AVINZA during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated. • breastfeeding. AVINZA passes into breast milk and may harm your baby. • taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking AVINZA with certain other medicines can cause serious side effects.
When taking AVINZA: • Do not change your dose. Take AVINZA exactly as prescribed by your healthcare provider. • Take your prescribed dose every 24 hours, at the same time every day. Do not take more than your prescribed dose in 24 hours. If you miss a dose, take your next dose at your usual time the next day. • Swallow AVINZA whole. Do not cut, break, chew, crush, dissolve, snort, or inject AVINZA because this may cause you to overdose and die. • 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 containing alcohol. Using products containing alcohol during treatment with AVINZA may cause you to overdose and die.
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, light-headedness when changing positions, 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: Pfizer Inc, New York, NY 10017 by: Alkermes Gainesville LLC, Gainesville, GA, 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 healthcare provider 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 applesauce, as follows:

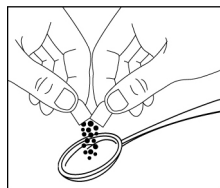


Figure 1

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

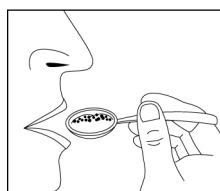


Figure 2

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



Figure 3

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



Figure 4

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

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

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured for: Pfizer Inc, New York, NY 10017
by: Alkermes Gainesville LLC, Gainesville, GA

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