



FOSAMPRENAVIR (TELZIR, Lexiva)

WHAT IS FOSAMPRENAVIR?

Fosamprenavir is a drug used for antiretroviral therapy (ART). It is also called Lexiva™. In some countries, it is called Telzir. It is manufactured by GlaxoSmithKline. Fosamprenavir is a pro-drug. The drug you swallow is not active against HIV. It breaks down in the body to produce the active form, which is the drug amprenavir (see Fact Sheet 445). Fosamprenavir was formerly called GW433908, or 908.

Fosamprenavir is a protease inhibitor. These drugs prevent the protease enzyme from working. HIV protease acts like a chemical scissors. It cuts the raw material for HIV into specific pieces needed to build a new virus. Protease inhibitors “gum up” these scissors.

WHO SHOULD TAKE IT?

Fosamprenavir was approved in 2003 as an antiretroviral (ARV) drug for people with HIV infection. In 2007 a liquid version was approved for patients ages 2 to 18.

There are no absolute rules about when to start ARV drugs. You and your doctor should consider your CD4 (T-cell) count, your viral load, any symptoms you are having, and your attitude about taking HIV medications. Fact Sheet 404 has more information about guidelines for the use of ARV medications.

If you take fosamprenavir with other ARV drugs, you can reduce your viral load to extremely low levels, and increase your CD4 counts. This should mean staying healthier longer.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. They are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV drug. When this happens, the drug will stop working. This is called “developing resistance” to the drug. See Fact Sheet 126 for more information on resistance.

Sometimes, if your virus develops resistance to one drug, it will also have resistance to other ARV drugs. This is called “cross-resistance”. Fosamprenavir might not be cross-resistant with other protease inhibitors. **Resistance can**

develop quickly. It is very important to **take ARV medications according to instructions, on schedule, and not to skip or reduce doses.**

HOW IS IT TAKEN?

Fosamprenavir is available as a tablet. The normal adult dose is 1400 milligrams (mg) two times a day. The tablets are 700 mg, so you will take 2 tablets at a time. Fosamprenavir can also be taken in various combinations with ritonavir to boost blood levels. The exact dosing depends on whether you have already used any antiviral treatment, or any other protease inhibitor medication. Be sure that your health care provider knows your medication history.

A liquid form of fosamprenavir is also available.

The dose for children should be calculated based on their body weight.

If you have liver problems or damage, talk to your doctor. You may need an adjusted dose of fosamprenavir.

Fosamprenavir is available as 700 mg tablets. It can be taken with or without food. It should be stored at room temperature. If you take fosamprenavir with ritonavir, be sure to keep the ritonavir in your refrigerator, or for up to 30 days at room temperature (below 77 degrees F, or 25 degrees C). Unlike the original version of amprenavir, fosamprenavir does not contain Vitamin E.

WHAT ARE THE SIDE EFFECTS?

The most common side effects are nausea, diarrhea, vomiting, rash, and headache. Some patients also felt numbness around the mouth, and abdominal pain. Less than 1% of people get serious skin reactions, including Stevens-Johnson syndrome. No other side effects seem to be very serious. The diarrhea in most cases can be controlled with over-the-counter medications.

Fosamprenavir can increase triglycerides (a blood fat). See Fact Sheet 123 for more information on blood fats. However, fosamprenavir might cause less of an increase in cholesterol than other protease inhibitors.

Fosamprenavir is a sulfa drug. If you are allergic to sulfa drugs, be sure to tell your doctor.

HOW DOES IT REACT WITH OTHER DRUGS?

Fosamprenavir is broken down by the liver and can interact with other drugs that also use the liver. **Combining these drugs can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. Make sure that your doctor knows about ALL drugs and supplements you are taking.**

Drugs to watch out for include other ARVs, drugs to treat tuberculosis (see fact sheet 518), erectile dysfunction (such as Viagra), heart rhythm (antiarrhythmics), and migraine headaches. Interactions are also possible with several antihistamines, sedatives, drugs to lower cholesterol and anti-fungal drugs.

- Fosamprenavir should **not** be combined with **Kaletra**. Blood levels of both lopinavir and fosamprenavir are reduced. More side effects were observed.
- If fosamprenavir is taken with ritonavir and **efavirenz**, the daily dosage of ritonavir may need to be increased.
- Some **birth control pills** may not work if you are taking fosamprenavir. Talk to your doctor about how to prevent an unwanted pregnancy.
- Fosamprenavir causes major increases in blood levels of some **antidepressants** like Elavil and Tofranil. These drugs are sometimes used to treat peripheral neuropathy (see fact sheet 555.) However, Fosamprenavir decreases blood levels of Paxil (paroxetine), an antidepressant. A dose increase of Paxil may be needed. Discuss use of antidepressants with your doctor.
- Fosamprenavir levels do not appear to be affected by use of antacids.
- Taking fosamprenavir with **methadone** can lower blood levels of both drugs. Check with your doctor if you use methadone. Watch for signs of excessive sedation with **buprenorphine**.
- The herb **St. John's Wort** (See Fact Sheet 729) lowers the blood levels of some protease inhibitors. Do not take it while taking fosamprenavir.
- Fosamprenavir increases blood levels of several “**statin**” drugs used to lower cholesterol levels. Some statins should not be used. The dose of others should be reduced.

Revised October 19, 2007