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PATIENT INFORMATION
FOSAMPRENAVIR
(foss-am-PREN-ah-ver)
CALCIUM TABLETS, USP
Rx only

What is the most important information I should know about fosamprenavir calcium tablets?

Fosamprenavir calcium tablets can interact with other medicines and cause serious side effects. It is important to know the medicines that should not be taken with fosamprenavir calcium tablets. See the section "Who should not take fosamprenavir calcium tablets?"

Fosamprenavir calcium tablets can cause serious side effects, including:

- **Severe skin reactions.** fosamprenavir calcium tablets may cause severe or life-threatening skin reactions or rash.

If you get a rash with any of the following symptoms, stop taking fosamprenavir calcium tablets and call your healthcare provider or get medical help right away:

- hives or sores in your mouth, or your skin blisters and peels
- swelling of your face, eyes, lips, tongue, or throat
- trouble swallowing or breathing

For more information about side effects, see "What are the possible side effects of fosamprenavir calcium tablets?"

What are fosamprenavir calcium tablets?

Fosamprenavir calcium tablets are prescription medicines that are used together with other antiretroviral medicines to treat human immunodeficiency virus 1 (HIV-1) infection.

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

It is not known if fosamprenavir calcium tablets are safe and effective in children younger than 4 weeks of age.

Do not take fosamprenavir calcium tablets if you:

- **are allergic** to amprenavir, fosamprenavir calcium, or any of the ingredients in fosamprenavir calcium tablets. See the end of this leaflet for a complete list of ingredients in fosamprenavir calcium tablets.

- **take any of the following medicines:**

- alfuzosin
- rifampin
- ergot including:
 - dihydroergotamine mesylate
 - ergonovine
 - ergotamine tartrate
 - methylergonovine
- cisapride
- St. John's wort (*Hypericum perforatum*)
- lomitapide
- lovastatin
- simvastatin
- pimozone
- delavirdine mesylate
- sildenafil (Revatio), for treatment of pulmonary arterial hypertension
- triazolam
- midazolam, when taken by mouth

Serious problems can happen if you or your child take any of the medicines listed above with fosamprenavir calcium tablets.

If you are taking fosamprenavir calcium tablets with ritonavir, do not take the following medicines:

- flecainide
- propafenone
- lurasidone

Before taking fosamprenavir calcium tablets, tell your healthcare provider about all of your medical conditions, including if you:

- are allergic to medicines that contain sulfa.
- have or have had liver problems, including hepatitis B or C virus infection.
- have kidney problems.
- have high blood sugar (diabetes).
- have hemophilia.
- have high cholesterol.
- are pregnant or plan to become pregnant. It is not known if fosamprenavir calcium tablets will harm your unborn baby. Talk to your healthcare provider if you are pregnant or plan to become pregnant during treatment with fosamprenavir calcium tablets.
- fosamprenavir calcium tablets may reduce how well hormonal contraceptives (birth control pills) work. Females who may become pregnant should use a different form of birth control or an additional barrier method of birth control during treatment with fosamprenavir calcium tablets.

Pregnancy Registry. There is a pregnancy registry for women who take fosamprenavir calcium tablets during pregnancy. The purpose of the registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take fosamprenavir calcium tablets.**

- You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.
- It is not known if fosamprenavir calcium tablets can pass to your baby in your breast milk.
- Talk with your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with fosamprenavir calcium tablets. Keep a list of your medicines to show your healthcare provider and pharmacist.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with fosamprenavir calcium tablets.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take fosamprenavir calcium tablets with other medicines.

How should I take fosamprenavir calcium tablets?

- **Take fosamprenavir calcium tablets exactly as your healthcare provider tells you to take it.**
- If you miss a dose of fosamprenavir calcium tablets, take it as soon as you remember. Do not take 2 doses at the same time or take more than your healthcare provider tells you to take.
- Stay under the care of a healthcare provider during treatment with fosamprenavir calcium tablets.
- If your child is taking fosamprenavir calcium tablets, your child's healthcare provider will decide the right dose based on your child's weight.
- fosamprenavir calcium tablets may be taken with or without food.
- Do not run out of fosamprenavir calcium tablets. The virus in

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your blood may increase and the virus may become harder to treat. When your supply starts to run low, get more from your healthcare provider or pharmacy.

- If you take too much fosamprenavir calcium tablets, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of fosamprenavir calcium tablets?

Fosamprenavir calcium tablets may cause serious side effects including:

- **See “What is the most important information I should know about fosamprenavir calcium tablets?”**
- **Liver problems.** Your healthcare provider should do blood tests before and during your treatment with fosamprenavir calcium tablets to check your liver function. Some people with liver problems, including hepatitis B or C, may have an increased risk of developing worsening liver problems during treatment with fosamprenavir calcium tablets.
- **Diabetes and high blood sugar (hyperglycemia).** Some people who take protease inhibitors, including fosamprenavir calcium tablets, can get high blood sugar, develop diabetes, or your diabetes can get worse. Tell your healthcare provider if you notice an increase in thirst or urinate often during treatment with fosamprenavir calcium tablets.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Call your healthcare provider right away if you start having new symptoms after starting your HIV-1 medicine.
- **Increase in body fat.** An increase in body fat can happen in people who take protease inhibitors, including fosamprenavir calcium tablets. The exact cause and long-term health effects of these conditions are not known.
- **Changes in blood tests.** Some people have changes in blood tests while taking fosamprenavir calcium tablets. These include an increase in liver function tests, blood fat levels (cholesterol and triglycerides) and decrease in red blood cells. Your healthcare provider should do regular blood tests before and during your treatment with fosamprenavir calcium tablets.
- **Increased bleeding problems in some people with hemophilia.** Some people with hemophilia have increased bleeding with protease inhibitors, including fosamprenavir calcium tablets.
- **Kidney stones.** Some people have developed kidney stones during treatment with fosamprenavir calcium tablets. Tell your healthcare provider right away if you develop any of the following signs or symptoms of kidney stones:
 - pain in your side
 - blood in your urine
 - pain when you urinate

The most common side effects of fosamprenavir calcium tablets in adults include:

- nausea
- vomiting
- rash
- diarrhea
- headache

The most common side effects of fosamprenavir calcium tablets in children include vomiting and decrease in white blood cells. These are not all the possible side effects of fosamprenavir calcium tablets.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store fosamprenavir calcium tablets?

- Store fosamprenavir calcium tablets at room temperature between 68° F to 77° F (20° C to 25° C).

- Keep the bottle of fosamprenavir calcium tablets tightly closed. Protect from moisture.

Keep fosamprenavir calcium tablets and all medicines out of the reach of children.

General information about the safe and effective use of fosamprenavir calcium tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use fosamprenavir calcium tablets for a condition for which it was not prescribed. Do not give fosamprenavir calcium tablets to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about fosamprenavir calcium tablets that is written for health professionals.

What are the ingredients in fosamprenavir calcium tablets?

Active ingredient: fosamprenavir calcium

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, microcrystalline cellulose, and povidone. The tablet coating contains the inactive ingredients ethylcellulose, ferric oxide red, hypromellose, talc, and titanium dioxide. The imprinting ink contains the inactive ingredients ferric oxide black, propylene glycol, and shellac.

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