



HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use FOSAMPRENAVIR CALCIUM TABLETS safely and effectively. See the full prescribing information for FOSAMPRENAVIR CALCIUM TABLETS.

WARNINGS AND PRECAUTIONS
The concomitant use of fosamprenavir calcium with ritonavir and certain other drugs may result in known or potentially significant drug interactions.

Table with 3 columns: Concomitant Drug Class, Drug Name, Effect on Concentration of Amprenavir or Concomitant Drug, Clinical Comment.

PATIENT INFORMATION
FOSAMPRENAVIR (fos-am-PREN-ah-ver) CALCIUM TABLETS
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.

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 face, eyes, lips, your skin or blisters on your tongue, throat and peels

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.

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.

are allergic to amprenavir, fosamprenavir calcium, or any of the ingredients in fosamprenavir calcium tablets.

take any of the following medicines: alizuzon, rifampin, ergot including: dihydroergotamine mesylate, ergonovine, ergotamine tartrate, methylergovanine

St. John's wort (Hypericum perforatum), lomitapide, simvastatin, pimozide, delavirdine mesylate, sildenaflil (REVATIO), for treatment of pulmonary arterial hypertension

triazolam, 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, or lorazepam

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.

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.

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 your blood may

FULL PRESCRIBING INFORMATION: CONTENTS
1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
3 CONTRAINDICATIONS
4 WARNINGS AND PRECAUTIONS

7 DRUG INTERACTIONS
8 USE IN SPECIFIC POPULATIONS
10 OVERDOSAGE
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY

2.1 General Dosage Information
Fosamprenavir calcium tablets may be taken with or without food. Adults should take fosamprenavir calcium oral suspension without food.

13 NONCLINICAL TOXICOLOGY
14 CLINICAL STUDIES
15 HOW SUPPLIED/STORAGE AND HANDLING
16 PATIENT COUNSELING INFORMATION

2.2 Adults
Fosamprenavir calcium tablets 1,400 mg twice daily (without ritonavir)
Fosamprenavir calcium tablets 1,400 mg once daily plus ritonavir 100 mg once daily

17.1 Laboratory Abnormalities
ALT (> 5 x ULN) 8%
AST (> 5 x ULN) 4%

2.3 Pediatric Patients (Aged at Least 4 Weeks to 18 Years)
The recommended dosage of fosamprenavir calcium tablets for pediatric patients aged at least 4 weeks to 18 years should be calculated based on body weight (kg) and should not exceed the recommended adult dose.

17.2 Laboratory Abnormalities Reported in Greater than or Equal to 2% of Antiretroviral-Naive Adult Subjects in Trial APV30002
Fosamprenavir Calcium 1,400 mg and Ritonavir 100 mg Twice Daily (n = 104)

Table with 3 columns: Weight, Fosamprenavir Calcium 45 mg/kg plus ritonavir 7 mg/kg, Fosamprenavir Calcium 35 mg/kg plus ritonavir 3 mg/kg

Table with 2 columns: Laboratory Abnormality, Fosamprenavir Calcium 1,400 mg and Ritonavir 100 mg Twice Daily (n = 104)

3 CONTRAINDICATIONS
Fosamprenavir calcium is contraindicated in patients with previously demonstrated clinically significant hypersensitivity (e.g., Stevens-Johnson syndrome) to any of the components of the product or to any of the components of the formulation.

17.3 Laboratory Abnormalities Reported in Greater than or Equal to 2% of Pediatric Patients in Trial APV30003
Triphosphates (> 150 mg/dL) 8%

4 WARNINGS AND PRECAUTIONS
Fosamprenavir calcium is contraindicated when administered with the following drugs:
- Amino glycosides (amikacin, gentamicin, tobramycin) (with ritonavir)

17.4 Laboratory Abnormalities Reported in Greater than or Equal to 2% of Pediatric Patients in Trial APV30003
Triphosphates (> 150 mg/dL) 8%

5.1 Risk of Serious Adverse Reactions Due to Drug Interactions
Initiation of fosamprenavir calcium/ritonavir, a CYP3A4 inhibitor, in patients receiving medications may increase plasma concentrations of these medications.

17.5 Laboratory Abnormalities Reported in Greater than or Equal to 2% of Pediatric Patients in Trial APV30003
Triphosphates (> 150 mg/dL) 8%

5.2 Acute Toxicity
Use of fosamprenavir calcium with ritonavir at higher than recommended dosages may result in transaminase elevations and should not be used.

17.6 Laboratory Abnormalities Reported in Greater than or Equal to 2% of Pediatric Patients in Trial APV30003
Triphosphates (> 150 mg/dL) 8%

5.3 Allergic Reaction
Fosamprenavir calcium should be used with caution in patients with a known sulfonamide allergy. Fosamprenavir contains a sulfonamide moiety.

17.7 Laboratory Abnormalities Reported in Greater than or Equal to 2% of Pediatric Patients in Trial APV30003
Triphosphates (> 150 mg/dL) 8%

5.4 Immune Reconstitution Syndrome
Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy, including fosamprenavir calcium. During the initial phase of combination antiretroviral treatment, patients whose immune systems respond may develop an inflammatory response to incident or residual opportunistic infections.

17.8 Laboratory Abnormalities Reported in Greater than or Equal to 2% of Pediatric Patients in Trial APV30003
Triphosphates (> 150 mg/dL) 8%

5.5 Hepatitis
Cases of hepatitis B were reported during postmarketing surveillance in HIV-1 infected patients receiving fosamprenavir calcium. In some cases, hepatitis B was reported during postmarketing surveillance in HIV-1 infected patients receiving fosamprenavir calcium.

17.9 Laboratory Abnormalities Reported in Greater than or Equal to 2% of Pediatric Patients in Trial APV30003
Triphosphates (> 150 mg/dL) 8%

5.6 Central Nervous System
Fosamprenavir calcium should be used with caution in patients with a history of seizures. Fosamprenavir contains a sulfonamide moiety.

17.10 Laboratory Abnormalities Reported in Greater than or Equal to 2% of Pediatric Patients in Trial APV30003
Triphosphates (> 150 mg/dL) 8%

5.7 Lactation
Fosamprenavir calcium is contraindicated in nursing women. Fosamprenavir is excreted in human milk. Because of the potential for adverse effects on the nursing infant, nursing should be discontinued during treatment with fosamprenavir calcium.

17.11 Laboratory Abnormalities Reported in Greater than or Equal to 2% of Pediatric Patients in Trial APV30003
Triphosphates (> 150 mg/dL) 8%

5.8 Laboratory Abnormalities
Laboratory abnormalities were reported in patients receiving fosamprenavir calcium. The mechanism and long-term consequences of these events are currently unknown.

17.12 Laboratory Abnormalities Reported in Greater than or Equal to 2% of Pediatric Patients in Trial APV30003
Triphosphates (> 150 mg/dL) 8%

Table with 4 columns: Adverse Reaction, Fosamprenavir Calcium 1,400 mg and Ritonavir 100 mg Twice Daily (n = 106), Fosamprenavir Calcium 1,250 mg and Ritonavir 200 mg Once Daily (n = 322)

Table with 4 columns: Adverse Reaction, Fosamprenavir Calcium 1,400 mg and Ritonavir 100 mg Twice Daily (n = 106), Fosamprenavir Calcium 1,250 mg and Ritonavir 200 mg Once Daily (n = 322)

Table with 4 columns: Adverse Reaction, Fosamprenavir Calcium 700 mg and Ritonavir 50 mg Twice Daily (n = 106), Lopinavir 400 mg and Ritonavir 150 mg Twice Daily (n = 103)

Table with 4 columns: Adverse Reaction, Fosamprenavir Calcium 700 mg and Ritonavir 50 mg Twice Daily (n = 106), Lopinavir 400 mg and Ritonavir 150 mg Twice Daily (n = 103)

PLR Size : 350 x 70 mm
Font Size : 6 Pt.
Track : A08/08/2019, A09/08/2019, A17/08/2019, A20/08/2019, A21/08/2019, A23/08/2019

