

Questions to Ask Your Doctor

1. Is ATRIPLA an appropriate regimen for me?
2. How will we know if ATRIPLA is working?
3. Is taking ATRIPLA the same as taking SUSTIVA® (efavirenz) and TRUVADA® (emtricitabine/tenofovir disoproxil fumarate)?
4. If I take ATRIPLA, will I have to take any other HIV meds?
5. What are the possible side effects of ATRIPLA?
6. If I experience side effects, what should I do?
7. What if I forget to take a dose of ATRIPLA?
8. How can I get help paying for my HIV medications?
9. Should I take ATRIPLA if I am pregnant or nursing?

INDICATION

ATRIPLA is a prescription medication used alone as a complete regimen or with other anti-HIV-1 medicines to treat HIV-1 infection in adults.

ATRIPLA does not cure HIV-1 infection or AIDS and has not been shown to lower your chance of passing HIV-1 to others through sexual contact, sharing needles, or being exposed to your blood. The long-term effects of ATRIPLA are not known at this time. People taking ATRIPLA may still get infections that develop because the immune system is weak or other conditions that happen with HIV-1 infection.

Do not change or stop your medicine without first talking with your healthcare provider. See your healthcare provider regularly while taking ATRIPLA.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about ATRIPLA?

ATRIPLA can cause serious side effects:

- **Some people who have taken medicine like ATRIPLA (which contains nucleoside analogs) have developed lactic acidosis** (build up of an acid in the blood). **Lactic acidosis can be a serious medical emergency that can lead to death.**

Call your healthcare provider right away if you get the following signs or symptoms of lactic acidosis:

- feel very weak or tired
- have unusual (not normal) muscle pain
- have trouble breathing
- have stomach pain with nausea and vomiting
- feel cold, especially in your arms and legs
- feel dizzy or lightheaded
- have a fast or irregular heartbeat

- **Some people who have taken medicines like ATRIPLA have developed serious liver problems (hepatotoxicity), with liver enlargement (hepatomegaly) and fat in the liver (steatosis). In some cases, these liver problems can lead to death.**

Call your healthcare provider right away if you get the following signs or symptoms of liver problems:

- skin or the white part of your eyes turns yellow (jaundice)
- urine turns dark
- bowel movements (stools) turn light in color
- don't feel like eating food for several days or longer
- feel sick to your stomach (nausea)
- have lower stomach area (abdominal) pain

- **You may be more likely to get lactic acidosis or liver problems** if you are female, very overweight (obese), or have been taking nucleoside analog-containing medicines, like ATRIPLA, for a long time.
- **If you also have hepatitis B virus (HBV) infection and you stop taking ATRIPLA, you may get a “flare-up” of your hepatitis. A “flare-up” is when the disease suddenly returns in a worse way than before.** Patients with HBV who stop taking ATRIPLA need close medical follow-up for several months to check for hepatitis that could be getting worse. ATRIPLA is not approved for the treatment of HBV, so you need to discuss your HBV therapy with your healthcare provider.

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Important Safety Information (continued)

Who should not take ATRIPLA?

You and your healthcare provider should decide if ATRIPLA is right for you. Do not take ATRIPLA if you are allergic to ATRIPLA or any of its ingredients.

What should I tell my healthcare provider before taking ATRIPLA?

Tell your healthcare provider if you:

- **Are pregnant or planning to become pregnant: Women should not become pregnant while taking ATRIPLA and for 12 weeks after stopping ATRIPLA.** Serious birth defects have been seen in children of women treated during pregnancy with one of the medicines in ATRIPLA. Women must use a reliable form of barrier contraception, such as a condom or diaphragm, even if they also use other methods of birth control, while on ATRIPLA and for 12 weeks after stopping ATRIPLA. Women should not rely only on hormone-based birth control, such as pills, injections, or implants, because ATRIPLA may make these contraceptives ineffective.
- **Are breastfeeding: Women with HIV should not breastfeed** because they can pass HIV through their milk to the baby. Also, ATRIPLA may pass through breast milk and cause serious harm to the baby.
- **Have kidney problems or are undergoing kidney dialysis treatment**
- **Have bone problems**
- **Have liver problems, including hepatitis B or C virus infection.** Your healthcare provider may want to do tests to check your liver while you take ATRIPLA or may switch you to another medicine.
- **Have ever had mental illness or are using drugs or alcohol**
- **Have ever had seizures or are taking medicine for seizures.** Seizures have occurred in patients taking efavirenz, a component of ATRIPLA, generally in those with a history of seizures. If you have ever had seizures, or take medicine for seizures, your healthcare provider may want to switch you to another medicine or monitor you.

What important information should I know about taking other medicines with ATRIPLA?

ATRIPLA may change the effect of other medicines, including the ones for HIV-1, and may cause serious side effects. Your healthcare provider may change your other medicines or change their doses.

MEDICINES YOU SHOULD NOT TAKE WITH ATRIPLA

- Do not take ATRIPLA if you are taking the following medicines because serious and life-threatening side effects may occur when taken together: Vascor[®] (bepidil), Propulsid[®] (cisapride), Versed[®] (midazolam), Orap[®] (pimozide), Halcion[®] (triazolam), or ergot medications (for example, Wigraine[®] and Cafergot[®]).
- ATRIPLA should not be taken with: Combivir[®] (lamivudine/zidovudine), COMPLERA[™] (emtricitabine/rilpivirine/tenofovir disoproxil fumarate), EMTRIVA[®] (emtricitabine), Epivir[®] or Epivir-HBV[®] (lamivudine), Epzicom[®] (abacavir sulfate/lamivudine), SUSTIVA[®] (efavirenz), Trizivir[®] (abacavir sulfate/lamivudine/zidovudine), TRUVADA[®] (emtricitabine/tenofovir DF), or VIREAD[®] (tenofovir DF), because they contain the same or similar active ingredients as ATRIPLA.
- Vfend[®] (voriconazole) should not be taken with ATRIPLA since it may lose its effect or may increase the chance of having side effects from ATRIPLA.
- **Do not take St. John's wort (Hypericum perforatum), or products containing St. John's wort with ATRIPLA.** Taking St. John's wort may decrease ATRIPLA levels and lead to increased viral load, and possible resistance to ATRIPLA or cross-resistance to other anti-HIV-1 drugs.
- ATRIPLA should not be used with HEPSERA[®] (adefovir dipivoxil).

These are not all the medicines that may cause problems if you take ATRIPLA. Tell your healthcare provider about all prescription and nonprescription medicines, vitamins, or herbal supplements you are taking or plan to take.

What are the possible side effects of ATRIPLA?

ATRIPLA may cause the following additional serious side effects:

- **Serious psychiatric problems.** Severe depression, strange thoughts, or angry behavior have been reported by a small number of patients. Some patients have had thoughts of suicide, and a few have actually committed suicide. These problems may occur more often in patients who have had mental illness.
- **Kidney problems** (including decline or failure of kidney function). If you have had kidney problems, or take other medicines that may cause kidney problems, your healthcare provider should do regular blood tests. Symptoms that may be related to kidney problems include a high volume of urine, thirst, muscle pain, and muscle weakness.
- **Other serious liver problems.** Some patients have experienced serious liver problems, including liver failure resulting in transplantation or death. Most of these serious side effects occurred in patients with a chronic liver disease such as hepatitis infection, but there have also been a few reports in patients without any existing liver disease.
- **Changes in bone mineral density (thinning bones).** Lab tests show changes in the bones of patients treated with tenofovir DF, a component of ATRIPLA. Some HIV patients treated with tenofovir DF developed thinning of the bones (osteopenia), which could lead to fractures. Also, bone pain and softening of the bone (which may lead to fractures) may occur as a consequence of kidney problems. If you have had bone problems in the past, your healthcare provider may want to do tests to check your bones or may prescribe medicines to help your bones. Also, bone pain and bone softening may occur because of kidney problems.

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Important Safety Information (continued)

Common side effects:

- Patients may have dizziness, headache, trouble sleeping, drowsiness, trouble concentrating, and/or unusual dreams during treatment with ATRIPLA. These side effects may be reduced if you take ATRIPLA at bedtime on an empty stomach; they tend to go away after taking ATRIPLA for a few weeks. Tell your healthcare provider right away if any of these side effects continue or if they bother you. These symptoms may be more severe if ATRIPLA is used with alcohol and/or mood-altering (street) drugs.
- If you are dizzy, have trouble concentrating, and/or are drowsy, avoid activities that may be dangerous, such as driving or operating machinery.
- Rash is a common side effect that usually goes away without any change in treatment. Rash may be serious in a small number of patients. If you develop a rash, call your healthcare provider right away.
- Other common side effects include: tiredness, upset stomach, vomiting, gas, and diarrhea.

Other possible side effects:

- Changes in body fat have been seen in some people taking anti-HIV-1 medicines. Increase of fat in the upper back and neck, breasts, and around the trunk may happen. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these changes in body fat are not known.
- Skin discoloration (small spots or freckles) may also happen.
- In some patients with advanced HIV infection (AIDS), signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. If you notice any symptoms of infection, contact your healthcare provider right away.
- Additional side effects are inflammation of the pancreas, allergic reaction (including swelling of the face, lips, tongue, or throat), shortness of breath, pain, stomach pain, weakness, and indigestion.

This is not a complete list of side effects. Tell your healthcare provider or pharmacist if you notice any side effects while taking ATRIPLA.

You should take ATRIPLA once daily on an empty stomach. Taking ATRIPLA at bedtime may make some side effects less bothersome.

Please see Full Prescribing Information, including “**What is the most important information I should know about ATRIPLA**” in the Patient Information section on ATRIPLA.com.

Please see Full Prescribing Information, including **Boxed WARNINGS** for ATRIPLA and TRUVADA at www.gilead.com, and Full Prescribing Information for SUSTIVA at www.bms.com.



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