Patient Information
ATRIPLA® (uh TRIP luh)
(efavirenz, emtricitabine, and tenofovir disoproxil fumarate) tablets

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

ATRIPLA can cause serious side effects, including:

- **Worsening of hepatitis B virus (HBV) infection.** Your healthcare provider will test you for HBV before starting treatment with ATRIPLA. If you have HBV infection and take ATRIPLA, your HBV may get worse (flare-up) if you stop taking ATRIPLA. A "flare-up" is when your HBV infection suddenly returns in a worse way than before.
  - Do not stop taking ATRIPLA without first talking with your healthcare provider.
  - Do not run out of ATRIPLA. Refill your prescription or talk to your healthcare provider before your ATRIPLA is all gone.
  - If you stop taking ATRIPLA, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your HBV infection, or give you a medication to treat hepatitis B. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking ATRIPLA.

For more information about side effects see the section, **"What are the possible side effects of ATRIPLA?"**

What is ATRIPLA?

ATRIPLA is a prescription medicine that contains efavirenz, emtricitabine, and tenofovir disoproxil fumarate combined in 1 tablet. ATRIPLA is used alone as a complete regimen, or in combination with other anti-HIV-1 medicines to treat people with HIV-1 infection who weigh at least 88 lbs (40 kg).

It is not known if ATRIPLA is safe and effective for use in children with HIV-1 infection who weigh less than 88 lbs (40 kg).

Who should not take ATRIPLA?

Do not take ATRIPLA if you:

- are allergic to efavirenz
- take the medicine called voriconazole, elbasvir or grazoprevir

Ask your healthcare provider if you are not sure if you take any of these medicines.

Before taking ATRIPLA**, tell your healthcare provider about all of your medical conditions, including if you:**

- have liver problems, including hepatitis B or C virus infection
- have heart problems
- have or have had mental problems
- have a history of drug or alcohol abuse
- have nervous system problems
- have kidney problems or receive kidney dialysis treatment
- have bone problems
- have had seizures or take medicines used to treat seizures
- are pregnant or plan to become pregnant. ATRIPLA can harm your unborn baby. If you are able to become pregnant, your healthcare provider should do a pregnancy test before you start treatment with ATRIPLA. **You should not become pregnant during treatment with ATRIPLA and for 12 weeks after stopping treatment.** Tell your healthcare provider if you become pregnant or think you may be pregnant during treatment with ATRIPLA.
  - **Females who are able to become pregnant should use 2 effective forms of birth control (contraception) during treatment with ATRIPLA and for 12 weeks after stopping treatment.**
  - **A barrier form of birth control should always be used along with another type of birth**

control. Barrier forms of birth control may include condoms, contraceptive sponges, diaphragm with spermicide, and cervical cap.

- **Birth control methods that contain the hormone progesterone such as birth control pills, injections, vaginal rings, or implants, may not work as well while taking ATRIPLA.**
- Talk to your healthcare provider about birth control methods that may be right for you during treatment with ATRIPLA.
- **Pregnancy Registry:** There is a pregnancy registry for women who take ATRIPLA during pregnancy. The purpose of this 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. ATRIPLA can pass into your breast milk. Do not breastfeed 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.

Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

ATRIPLA and some medicines may interact with each other causing serious side effects.

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

How should I take ATRIPLA?

- Take ATRIPLA exactly as your healthcare provider tells you to.
- If you take ATRIPLA with other medicines used to treat HIV-1, your healthcare provider will tell you what medicines to take and how to take them.
- Take ATRIPLA 1 time each day on an empty stomach. You should take ATRIPLA at the same time each day.
- Taking ATRIPLA at bedtime may make some side effects less bothersome.
- **Do not miss a dose of ATRIPLA**. Missing a dose lowers the amount of medicine in your blood. Refill your ATRIPLA prescription before you run out of medicine.
- Do not change your ATRIPLA dose or stop taking ATRIPLA without first talking with your healthcare provider. Stay under a healthcare provider's care during treatment with ATRIPLA.
- If you take too much ATRIPLA, call your healthcare provider or got to the nearest hospital emergency room right away.

What should I avoid while taking ATRIPLA?

- ATRIPLA can cause dizziness, impaired concentration and drowsiness. If you have these symptoms, do not drive a car, use heavy machinery, or do anything that requires you to be alert.

What are the possible side effects of ATRIPLA?

ATRIPLA may cause serious side effects, including:

- **See "What is the most important information I should know about ATRIPLA?"**
- **Rash.** Rash is a serious side effect but may also be common. Rashes will usually go away without any change in your treatment. Tell your healthcare provider right away if you develop a rash during treatment with ATRIPLA.
- **Severe liver problems.** In rare cases, severe liver problems can happen that can lead to death. **Tell your healthcare provider right away if you get these symptoms:** skin or the white part of your eyes turns yellow, dark "tea-colored" urine, light-colored stools, loss of appetite for several days or longer, nausea, or stomach-area pain.
- **Mental problems.** Serious mental problems including severe depression, suicidal thoughts and actions, aggressive behavior, delusions, catatonia, and paranoid and manic reactions have happened in people who take ATRIPLA. These mental health problems may happen more often in people who

have a history of mental problems or drug use, or who take medicines to treat mental problems. Tell your healthcare provider right away if you develop serious mental problems during treatment with ATRIPLA.

Nervous system problems. Nervous system problems usually begin during the first or second day of treatment with ATRIPLA and usually go away after 2 to 4 weeks of treatment. Some symptoms may occur months to years after beginning ATRIPLA therapy. These symptoms may become more severe if you drink alcohol or take mood altering (street) drugs while taking ATRIPLA. Tell your healthcare provider right away if you develop nervous system problems during treatment with ATRIPLA. Symptoms of nervous system problems may include:

- dizziness
- problems concentrating
- abnormal dreams
- unusually happy mood
- agitation
- thought problems
- slow thoughts and physical movement
- problems sleeping
- excessive sleepiness or difficulty awakening
- seeing or hearing things that are not real (hallucinations)
- confusion
- memory problems
- lack of coordination or difficulty with balance

If you have dizziness, trouble concentrating or sleepiness, do not drive a car, use machinery, or do anything that needs you to be alert.

- **New or worse kidney problems, including kidney failure.** Your healthcare provider should do blood and urine tests to check your kidneys before you start and during treatment with ATRIPLA. Your healthcare provider may tell you to stop taking ATRIPLA if you develop new or worse kidney problems during treatment with ATRIPLA.
- **Bone problems** can happen in some people who take ATRIPLA. Bone problems include bone pain or softening or thinning of bones, which may lead to fractures. Your healthcare provider may need to do tests to check your bones.
- **Seizures.** Your healthcare provider may do blood tests during treatment with ATRIPLA if you take certain medicines used to prevent seizures.
- **Too much lactic acid in your blood (lactic acidosis).** Too much lactic acid is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you develop any of these symptoms:
  - weakness or being more tired than usual
  - being short of breath or fast breathing
  - cold or blue hands and feet
  - fast or abnormal heartbeat
  - unusual muscle pain
  - stomach pain with nausea and vomiting
  - feel dizzy or lightheaded
- **Changes in your immune system (Immune Reconstitution Syndrome) can happen when an HIV-1 infected person starts 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. Tell your healthcare provider right away if you develop any new symptoms after starting treatment with ATRIPLA.
- **Changes in body fat.** Changes in body fat distribution or accumulation have happened in some people taking HIV-1 medicines, including an increased amount of fat in the upper back and neck ("buffalo hump"), in the breasts, and around the trunk. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these body fat changes are not known.

The most common side effects of ATRIPLA include:

- diarrhea
- tiredness
- dizziness
- problems sleeping
- rash
- nausea
- headache
- depression
- abnormal dreams

These are not all the possible side effects of ATRIPLA.

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 ATRIPLA?

- Store ATRIPLA at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep ATRIPLA in its original container and keep the container tightly closed.

Keep ATRIPLA and all other medicines out of reach of children.

General information about the safe and effective use of ATRIPLA.

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

What are the ingredients of ATRIPLA?

Active Ingredients: efavirenz, emtricitabine, and tenofovir disoproxil fumarate

Inactive Ingredients: croscarmellose sodium, hydroxypropyl cellulose, magnesium sterate, microcrystalline cellulose, and sodium lauryl sulfate. The film coating contains black iron oxide, polyethylene glycol, polyvinyl alcohol, red iron oxide, talc, and titanium dioxide.

Manufactured and distributed by: Gilead Sciences, Inc. Foster City, CA 94404

For more information go to www.ATRIPLA.com or call 1-800-445-3235.

21937-GS-020

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised: October/2019