Atripla

WHAT IS ATRIPLA?

Atripla is a drug used as part of antiretroviral therapy (ART). Atripla contains three antiretroviral drugs (ARVs) combined in one tablet:

- efavirenz (EFV, Sustiva)
- emtricitabine (FTC, Emtriva)
- tenofovir disoproxil fumarate (tenofovir DF, TDF, Viread)

The FDA approved Atripla in 2006 as an ARV for people with HIV infection. Generic versions have been approved for sale under the President's Emergency Plan for AIDS Relief (PEPFAR). Atripla is manufactured by Gilead Sciences.

One of the drugs in Atripla, efavirenz, is a type of drug called a non-nucleoside reverse transcriptase inhibitor (NNRTI). The other two drugs, emtricitabine and tenofovir DF, are nucleoside reverse transcriptase inhibitors (NRTIs). NRTIs and NNRTIs bind to and block reverse transcriptase (an HIV enzyme). HIV uses reverse transcriptase to convert its RNA into DNA (reverse transcription). Blocking reverse transcriptase and reverse transcription prevents HIV from replicating.

When used alone as a complete HIV regimen or in combination with other ARVs to treat HIV infection, Atripla may help:

- Reduce the amount of HIV in your blood. This is called viral load.
- Increase the number of CD4 cells in your blood that help fight off other infections.

Reducing the amount of HIV and increasing the CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting opportunistic infections (OIs) that can happen when your immune system is weak. Read more about viral suppression.

Atripla does not cure HIV infection or AIDS. You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

WHO SHOULD TAKE ATRIPLA?

Atripla is a prescription three-drug fixed-dose combination medication to treat HIV infection in adults and children weighing at least 88 pounds (40 kg). The safety and effectiveness of Atripla has not been established in children weighing less than 88 pounds (40 kg). Atripla has not been carefully studied in the elderly (65

years of age and older).

All people living with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. Read more about U.S. ART guidelines.

Atripla provides three drugs in one pill. It can be more convenient to use Atripla than some other combinations of drugs that must be taken separately or at different times of the day. This could mean fewer missed doses and better control of HIV. Atripla is indicated as a complete regimen or in combination with other ARVs.

WHO SHOULD NOT TAKE ATRIPLA?

Do not take Atripla if you are allergic to efavirenz, emtricitabine, tenofovir DF, or any of the ingredients in this drug.

Do not take Atripla if you are taking any of the following medicines. Taking Atripla with these medicines may affect how Atripla works. Atripla may cause serious or life-threatening side effects or death when used with these medicines:

- Anti-fungal medicine: voriconazole
- Hepatitis C virus (HCV) medicines: elbasvir, grazoprevir

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any of these medicines in the past four weeks, talk to your healthcare provider or pharmacist before starting treatment with Atripla.

Atripla is not recommended in people with moderate to severe kidney or liver disease.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING ATRIPLA?

Before you take Atripla, tell your healthcare provider about all of your medical conditions, and in particular if you:

- Have or have had liver problems, including hepatitis B virus (HBV) or HCV infection
- Have heart problems
- Have or have had mental health 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 or have had seizures or take medicines used to treat seizures

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with with Atripla. Atripla can harm your unborn baby. If you can become pregnant, your healthcare provider will perform a pregnancy test before you start treatment with Atripla and you should consistently 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,

diaphragms with spermicide, and cervical caps. 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.

There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. Read more about pregnancy and HIV.

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with Atripla. Atripla can pass to your baby in your breast milk. Do not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. Read more about HIV drug resistance.

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS ATRIPLA TAKEN?

Atripla is taken by mouth as a tablet. Each Atripla tablet contains 600 mg of efavirenz, 200 mg of emtricitabine, and 300 mg of tenofovir DF. The recommended dosage of Atripla in adults and children who weigh at least 88 pounds (40 kg) is one tablet once daily.

You should take Atripla at bedtime on an empty stomach. Taking Atripla at bedtime may make some side effects less bothersome. You should take Atripla at the same time each day.

If you take Atripla with other ARVs, your healthcare provider will tell you what medicines to take and how to take them.

WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary side effects such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of Atripla are diarrhea, tiredness, dizziness, problems sleeping, rash, nausea, headaches, depression, and abnormal dreams.

Atripla can cause serious side effects including:

Worsening of 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 (flareup) 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 to 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 HBV. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking 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:

- Your skin or the white part of your eyes turns yellow
- Dark or “tea-colored” urine
- Light-colored stools (bowel movements)
- Loss of appetite for several days or longer
- Nausea or vomiting
- Stomach-area pain

Mental health problems. Serious mental health 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 2-4 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 any of the following nervous system problems during treatment with Atripla:

- 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 requires 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. 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). Lactic acidosis is a serious but rare medical emergency that can cause 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

Immune Reconstitution Inflammatory Syndrome (IRIS). IRIS is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience 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 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.

These are not all the possible side effects of Atripla. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW DOES ATRIPLA REACT WITH OTHER DRUGS?

All ARVs can interact with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take Atripla with other medicines.

See above for a list of medicines that should not be taken with Atripla.

MORE INFORMATION

Visit the Atripla website.

Download the full Prescribing Information.

Download the Patient Information leaflet.

Apply for the Gilead Advancing Access Program.

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