IMPORTANT SAFETY INFORMATION (continued)

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.

Common side effects:

- Patients may have dizziness, headache, trouble sleeping, drowsiness, trouble concentrating, and/or unusual dreams during treatment with ATRIPLA (efavirenz/emtricitabine/tenofovir disoproxil fumarate). 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 with ATRIPLA that usually goes away without any change in treatment. Rash may be serious in a small number of patients. **Rash occurs more commonly in children and may be a serious problem.** If a rash develops, 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 the following Patient Information for more information about these warnings, including signs and symptoms, and other Important Safety Information.

Bristol-Myers Squibb

Patient Information

℞ ONLY

ATRIPLA® (uh TRIP luh) Tablets

ALERT: Find out about medicines that should NOT be taken with ATRIPLA (efavirenz/emtricitabine/tenofovir disoproxil fumarate).

Please also read the section **"MEDICINES YOU SHOULD NOT TAKE WITH ATRIPLA."**

Generic name: efavirenz, emtricitabine and tenofovir disoproxil fumarate (eh FAH vih renz, em tri SIT uh bean and te NOE' fo veer dye soe PROX il FYOU mar ate)

Read the Patient Information that comes with ATRIPLA before you start taking it and each time you get a refill since there may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. You should stay under a healthcare provider's care when taking ATRIPLA. **Do not change or stop your medicine without first talking with your healthcare provider.** Talk to your healthcare provider or pharmacist if you have any questions about ATRIPLA.

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

- **Some people who have taken medicine like ATRIPLA (which contains nucleoside analogs) have developed a serious condition called lactic acidosis** (build up of an acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital. **Call your healthcare provider right away if you get the following signs or symptoms of lactic acidosis:**
- You feel very weak or tired.
- You have unusual (not normal) muscle pain.
- You have trouble breathing.
- You have stomach pain with nausea and vomiting.
- You feel cold, especially in your arms and legs.
- You feel dizzy or lightheaded.
- You have a fast or irregular heartbeat.
- **Some people who have taken medicines like ATRIPLA have developed serious liver problems called hepatotoxicity,** with liver enlargement (hepatomegaly) and fat in the liver (steatosis). **Call your healthcare provider right away if you get the following signs or symptoms of liver problems:**
- Your skin or the white part of your eyes turns yellow (jaundice).
- Your urine turns dark.
- Your bowel movements (stools) turn light in color.
- You don't feel like eating food for several days or longer.
- You feel sick to your stomach (nausea).
- You 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, including medical exams and blood tests to check for hepatitis that could be getting worse. ATRIPLA is not approved for the treatment of HBV, so you must discuss your HBV therapy with your healthcare provider.

What is ATRIPLA?

ATRIPLA contains 3 medicines, SUSTIVA® (efavirenz), EMTRIVA® (emtricitabine) and VIREAD® (tenofovir disoproxil fumarate also called tenofovir DF) combined in one pill. EMTRIVA and VIREAD are HIV-1 (human immunodeficiency virus) nucleoside analog reverse transcriptase inhibitors (NRTIs) and SUSTIVA is an HIV-1 non-nucleoside analog reverse transcriptase inhibitor (NNRTI). VIREAD and EMTRIVA are the components of TRUVADA®. ATRIPLA can be used alone as a complete regimen, or in combination with other anti-HIV-1 medicines to treat people with HIV-1 infection. ATRIPLA is for adults and children 12 years of age and older who weigh at least 40 kg (at least 88 lbs). ATRIPLA is not recommended for children younger than 12 years of age. ATRIPLA has not been studied in adults over 65 years of age.

HIV infection destroys CD4+ T cells, which are important to the immune system. The immune system helps fight infection. After a large number of T cells are destroyed, acquired immune deficiency syndrome (AIDS) develops.

ATRIPLA helps block HIV-1 reverse transcriptase, a viral chemical in your body (enzyme) that is needed for HIV-1 to multiply. ATRIPLA lowers the amount of HIV-1 in the blood (viral load). ATRIPLA may also help to increase the number of T cells (CD4+ cells), allowing your immune system to improve. Lowering the amount of HIV-1 in the blood lowers the chance of death or infections that happen when your immune system is weak (opportunistic infections).

Does ATRIPLA cure HIV-1 or AIDS?

ATRIPLA does not cure HIV-1 infection or AIDS and you may continue to experience illnesses associated with HIV-1 infection, including opportunistic infections. You should remain under the care of a doctor when using ATRIPLA.

Who should not take ATRIPLA?

Together with your healthcare provider, you need to decide whether ATRIPLA is right for you.

Do not take ATRIPLA if you are allergic to ATRIPLA or any of its ingredients. The active ingredients of ATRIPLA are efavirenz, emtricitabine, and tenofovir DF. See the end of this leaflet for a complete list of ingredients.