

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM

ATRIPLA® film-coated tablets (efavirenz, emtricitabine and tenofovir disoproxil)

Read this entire leaflet carefully before you start taking ATRIPLA.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

COMPOSITION

WHAT ATRIPLA CONTAINS

Active Ingredients: Efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg.

Inactive Ingredients: Croscarmellose sodium, hydroxypropyl cellulose, microcrystalline cellulose, magnesium stearate and sodium lauryl sulphate. The film-coating contains polyethylene glycol, polyvinyl alcohol, talc and titanium dioxide.

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ATRIPLA does not contain sugar.

WHAT ATRIPLA IS USED FOR

ATRIPLA contains 3 medicines: Efavirenz, emtricitabine and tenofovir disoproxil fumarate (also called tenofovir DF) combined in one pill. Emtricitabine and tenofovir are HIV (human immunodeficiency virus) nucleoside analogue reverse transcriptase inhibitors (NRTIs) and efavirenz is an HIV non-nucleoside analogue reverse transcriptase inhibitor (NNRTI).

ATRIPLA can be used alone as a complete regimen, or in combination with other anti-HIV medicines to treat people with HIV infection. ATRIPLA is for adults age 18 and over.

ATRIPLA has not been studied in children under age 18 or adults over age 65.

ATRIPLA helps block HIV reverse transcriptase, a viral chemical in your body (enzyme) that is needed for HIV to multiply. ATRIPLA lowers the amount of HIV 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 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 infection or AIDS. The long-term effects of ATRIPLA are not known at this time. People taking ATRIPLA may still get opportunistic infections or other conditions that happen with HIV infection. Opportunistic infections are infections that develop because the immune system is weak. Some of these conditions are pneumonia, herpes virus infections and *Mycobacterium avium complex* (MAC) infection. **It is very important that you see your healthcare provider regularly while taking ATRIPLA.**

Does ATRIPLA reduce the risk of passing HIV-1 to others?

ATRIPLA has not been shown to lower your chance of passing HIV to other people through sexual contact, sharing needles or being exposed to your blood.

- **Do not share needles or other injection equipment.**
- **Do not share personal items that can have blood or body fluids on them, like toothbrushes or razor blades.**
- **Do not have any kind of sex without protection.** Always practice safer sex by using a latex or polyurethane condom or other barrier to reduce the chance of sexual contact with semen, vaginal secretions or blood.

BEFORE YOU 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 **COMPOSITION**).

What should I tell my healthcare provider before taking ATRIPLA?

Tell your healthcare provider if you:

- **are pregnant or planning to become pregnant (see Pregnancy and breastfeeding)**
- **are breastfeeding (see Pregnancy and breastfeeding)**
- **have kidney problems or are undergoing kidney dialysis treatment**
- **have bone problems**
- **have liver problems, including Hepatitis B Virus infection.** Your healthcare provider may want to do tests to check your liver while you take ATRIPLA.
- **have ever had mental illness or are using medicines or alcohol**
- **have ever had seizures or are taking medicine for seizures.**

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, and may cause serious side effects. Your healthcare provider may change your other medicines or change their doses. Other medicines, including herbal products, may affect ATRIPLA. For this reason, **it is very important to** let all your healthcare providers and pharmacists know what medications, herbal supplements or vitamins you are taking.

MEDICINES YOU SHOULD NOT TAKE WITH ATRIPLA

- The following medicines may cause serious and life-threatening side effects when taken with ATRIPLA. You should not take any of these medicines while taking ATRIPLA: Astemizole, bepridil, cisapride, midazolam, pimozone, triazolam, ergot medications and ketoconazole.
- ATRIPLA also should not be used with lamivudine/zidovudine, emtricitabine, lamivudine, abacavir sulphate/lamivudine, abacavir sulphate/lamivudine/zidovudine, efavirenz, emtricitabine /tenofovir disoproxil fumarate or tenofovir disoproxil fumarate.
- Voriconazole should not be taken with ATRIPLA since it may lose its effect or may increase the chance of having side effects from ATRIPLA.

It is also important to tell your healthcare provider if you are taking any of the following:

- Saquinavir, clarithromycin or itraconazole; **these medicines may need to be replaced with another medicine when taken with ATRIPLA.**
- Calcium channel blockers such as diltiazem or verapamil and others; indinavir, rifabutin, rifampicin, cholesterol-lowering medicines such as atorvastatin, pravastatin sodium and simvastatin or sertraline; **these medicines may need to have their dose changed when taken with ATRIPLA.**

- Didanosine; tenofovir DF (a component of ATRIPLA) may increase the amount of didanosine in your blood, which could result in more side effects. **You may need to be monitored more carefully** if you are taking ATRIPLA and didanosine together. Also, the dose of didanosine may need to be changed.
- Atazanavir sulphate or lopinavir/ritonavir; these medicines may increase the amount of tenofovir DF (a component of ATRIPLA) in your blood, which could result in more side effects. **You may need to be monitored more carefully** if you are taking ATRIPLA and either atazanavir sulphate or lopinavir/ritonavir together. Also, the dose of atazanavir sulphate or lopinavir/ritonavir may need to be changed.
- Medicine for seizures (for example, phenytoin, carbamazepine or phenobarbital); your healthcare provider may want to switch you to another medicine or check medicine levels in your blood from time to time.
- **Taking St. John's wort (*Hypericum perforatum*), or products containing St. John's wort with ATRIPLA is not recommended.** St. John's wort is a herbal product sold as a dietary supplement. Talk with your healthcare provider if you are taking or are planning to take St. John's wort. 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 medicines.

These are not all the medicines that may cause problems if you take ATRIPLA. Be sure to tell your healthcare provider about all medicines that you take.

Keep a complete list of all the prescription and non-prescription medicines as well as any herbal remedies that you are taking, how much you take, and how often you take them.

Make a new list when medicines or herbal remedies are added or stopped, or if the dose changes. Give copies of this list to all of your healthcare providers and pharmacists **every** time you visit your healthcare provider or fill a prescription. This will give your healthcare

provider a complete picture of the medicines you use. Then he or she can decide the best approach for your situation.

Pregnancy and breastfeeding

You should not use ATRIPLA if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking ATRIPLA (see Do not breastfeed if you are taking ATRIPLA).

- **Women taking ATRIPLA should not become pregnant.** Serious birth defects have been seen in the babies of animals and women treated with efavirenz (a component of ATRIPLA) during pregnancy. It is not known whether efavirenz caused these defects. **Tell your healthcare provider right away if you are pregnant.** Also talk with your healthcare provider if you want to become pregnant.
- Women should not rely only on hormone-based birth control, such as pills, injections or implants, because ATRIPLA may make these contraceptives ineffective. 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.
- **Do not breastfeed if you are taking ATRIPLA.** The Centres for Disease Control and Prevention recommend that mothers with HIV not breastfeed because they can pass the HIV through their milk to the baby. Also, ATRIPLA may pass through breast milk and cause serious harm to the baby. Talk with your healthcare provider if you are breastfeeding. You should stop breastfeeding or may need to use a different medicine.

Use in Children

ATRIPLA is not recommended for patients less than 18 years of age.

Driving and using machinery

Dizziness, impaired concentration and drowsiness have been reported during treatment with the individual components of ATRIPLA. If you experience any of these symptoms while taking ATRIPLA, do **not** drive and do **not** use any tools or machines.

Taking other medicines with ATRIPLA

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

- Taking ATRIPLA with alcohol or other medicines causing similar side effects as ATRIPLA, such as drowsiness, may increase those side effects.
- Do not take any other medicines, including prescription and non-prescription medicines and herbal products, without checking with your healthcare provider.
- **Avoid doing things that can spread HIV infection** since ATRIPLA does not stop you from passing the HIV infection to others.

HOW TO TAKE ATRIPLA

- Take the exact amount of ATRIPLA your healthcare provider prescribes. Never change the dose on your own. Do not stop ATRIPLA unless your healthcare provider tells you to stop.
- You should take ATRIPLA on an empty stomach.
- Swallow ATRIPLA with water.
- Taking ATRIPLA at bedtime may make some side effects less bothersome.
- Do not miss a dose of ATRIPLA. If you forget to take ATRIPLA, take the missed dose right away, unless it is almost time for your next dose. Do not double the next dose.

Carry on with your regular dosing schedule. If you need help in planning the best times to take your medicine, ask your healthcare provider or pharmacist.

- If you believe you took more than the prescribed amount of ATRIPLA, contact your local poison control centre or emergency room right away.
- Tell your healthcare provider if you start any new medicine or change how you take old ones. Your doses may need adjustment.
- When your ATRIPLA supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to ATRIPLA and become difficult to treat.
- Your healthcare provider may want to do blood tests to check for certain side effects while you take ATRIPLA.

POSSIBLE SIDE EFFECTS

ATRIPLA may cause the following serious side effects:

- **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 signs of lactic acidosis.**
- **Serious liver problems (hepatotoxicity)**, with liver enlargement (hepatomegaly) and fat in the liver (steatosis). Call your healthcare provider right away if you get any signs of liver problems (see **What is the most important information I should know about ATRIPLA?**).
- **“Flare-ups” of Hepatitis B Virus (HBV) infection**, in which the disease suddenly returns in a worse way than before, can occur if you have HBV and you stop taking ATRIPLA. Your healthcare provider will monitor your condition for several months after stopping ATRIPLA if you have both HIV and HBV infection and may recommend treatment for your HBV.

- **Serious psychiatric problems.** A small number of patients may experience severe depression, strange thoughts, or angry behaviour while taking ATRIPLA. Some patients have thoughts of suicide and a few have actually committed suicide. These problems may occur more often in patients who have had mental illness. Contact your healthcare provider right away if you think you are having these psychiatric symptoms, so your healthcare provider can decide if you should continue to take ATRIPLA.
- **Kidney problems.** If you have had kidney problems in the past or take other medicines that can cause kidney problems, your healthcare provider should do regular blood tests to check your kidneys.
- **Changes in bone mineral density (thinning bones).** It is not known whether long-term use of ATRIPLA will cause damage to your bones. If you have had bone problems in the past, your healthcare provider may need to do tests to check your bone mineral density or may prescribe medicines to help your bone mineral density.

Other side effects include:

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. Tell your healthcare provider right away if any of these side effects continue or if they bother you. It is possible that these symptoms may be more severe if ATRIPLA is used with alcohol or mood altering (street) medicines.

If you are dizzy, have trouble concentrating, or are drowsy, avoid activities that may be dangerous, such as driving or operating machinery.

Rash is common. Rashes usually go away without any change in treatment. In a small number of patients, rash may be serious. If you develop a rash, call your healthcare provider right away.

- Changes in body fat. Changes in body fat develop in some patients taking ATRIPLA. These changes may include 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 fat changes are not known.
- Skin discolouration (small spots or freckles) may also happen with ATRIPLA.

Not all side effects reported for ATRIPLA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ATRIPLA, please consult your doctor, pharmacist or other healthcare professional for advice.

Contact your healthcare provider before stopping ATRIPLA because of side effects or for any other reason.

This is not a complete list of side effects possible with ATRIPLA. Ask your healthcare provider or pharmacist for a more complete list of side effects of ATRIPLA and all the medicines you will take.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

STORING AND DISPOSING

- **Keep ATRIPLA and all other medicines out of reach of children.**
- Store ATRIPLA at or below 30 °C.
- Keep ATRIPLA in its original container and keep the container tightly closed.
- The silica gel desiccant should not be removed from the bottle after opening.

Do not use ATRIPLA after the expiry date which is stated on the bottle label and carton after EXP.:. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

PRESENTATION

ATRIPLA Tablets are packed bottles of 30 tablets (with a silica gel desiccant that must be kept in the bottle to help protect your tablets). The silica gel desiccant should not be swallowed. The bottle is packed in a carton.

IDENTIFICATION

ATRIPLA Tablets are white, capsule-shaped, film-coated tablets, debossed with 123 on both sides of the tablet.

REGISTRATION NUMBER

42/20.2.8/0729

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