Package leaflet: Information for the patient

Atripla 600 mg/200 mg/245 mg film-coated tablets
Efavirenz/emtricitabine/tenofovir disoproxil

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Atripla is and what it is used for

Atripla contains three active substances that are used to treat human immunodeficiency virus (HIV) infection:

- Efavirenz is a non-nucleoside reverse transcriptase inhibitor (NNRTI)
- Emtricitabine is a nucleoside reverse transcriptase inhibitor (NRTI)
- Tenofovir is a nucleotide reverse transcriptase inhibitor (NtRTI)

Each of these active substances, also known as antiretroviral medicines, work by interfering with an enzyme (reverse transcriptase) that is essential for the virus to multiply.

Atripla is a treatment for Human Immunodeficiency Virus (HIV) infection in adults aged 18 years and over who have previously been treated with other antiretroviral medicines and have their HIV-1 infection under control for at least three months. Patients must not have experienced failure of a previous HIV therapy.

2. What you need to know before you take Atripla

Do not take Atripla

- **if you are allergic** to efavirenz, emtricitabine, tenofovir, tenofovir disoproxil or any of the other ingredients of this medicine (listed in section 6).

- **if you have severe liver disease.**

- **if you have a heart condition, such as an abnormal electrical signal called prolongation of the QT interval that puts you at high risk for severe heart rhythm problems (Torsade de Pointes).**

- if any member of your family (parents, grandparents, brothers or sisters) has died suddenly due to a heart problem or was born with heart problems.

- if your doctor has told you that you have high or low levels of electrolytes such as potassium or magnesium in your blood.

- **if you are currently taking** any of the following medicines (see also "Other Medicines and Atripla"):
  - **astemizole or terfenadine** (used to treat hay fever or other allergies)
  - **bepridil** (used to treat heart disease)
  - **cisapride** (used to treat heartburn)
  - **elbasvir/grazoprevir** (used to treat hepatitis C)
  - **ergot alkaloids** (for example, ergotamine, dihydroergotamine, ergonovine, and methylergonovine) (used to treat migraines and cluster headaches)
  - **midazolam or triazolam** (used to help you sleep)
  - **pimozide, imipramine, amitriptyline or clomipramine** (used to treat certain mental conditions)
  - **St. John's wort** (*Hypericum perforatum*) (a herbal preparation used for depression and anxiety)
  - **voriconazole** (used to treat fungal infections)
  - **flecainide, metoprolol** (used to treat irregular heart beat)
  - **certain antibiotics** (macrolides, fluoroquinolones, imidazole)
  - **triazole antifungal agents**
  - **certain antimalarial agents**
  - **methadone** (used to treat opiate addiction)

→**If you are taking any of these medicines, tell your doctor immediately.** Taking these medicines with Atripla could cause serious or life-threatening side effects or stop these medicines from working properly.

Warnings and precautions

Talk to your doctor or pharmacist before taking Atripla.

- **You can still pass on HIV** when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people. This medicine is not a cure for HIV infection. While taking Atripla you may still develop infections or other illnesses associated with HIV infection.

- You must remain under the care of your doctor while taking Atripla.

- **Tell your doctor:**

  - **if you are taking other medicines** that contain efavirenz, emtricitabine, tenofovir disoproxil, tenofovir alafenamide, or lamivudine or adefovir dipivoxil. Atripla should not be taken with any of these medicines.

  - **if you have or have had kidney disease,** or if tests have shown problems with your kidneys. Atripla is not recommended if you have moderate to severe kidney disease.

    Atripla may affect your kidneys. Before starting treatment, your doctor may order blood tests to assess kidney function. Your doctor may also order blood tests during treatment to monitor your kidneys.

    Atripla is not usually taken with other medicines that can damage your kidneys (see *Other medicines and Atripla*). If this is unavoidable, your doctor will monitor your kidney function once a week.

  - **if you have a heart disorder, such as abnormal electrical signal called prolongation of the QT interval.**

- **if you have a history of mental illness,** including depression, or of substance or alcohol abuse. Tell your doctor immediately if you feel depressed, have suicidal thoughts or have strange thoughts (see section 4, *Possible side effects*).

- **if you have a history of convulsions (fits or seizures)** or if you are being treated with anticonvulsant therapy such as carbamazepine, phenobarbital and phenytoin. If you are taking any of these medicines, your doctor may need to check the level of anticonvulsant medicine in your blood to ensure that it is not affected while taking Atripla. Your doctor may give you a different anticonvulsant.

- **if you have a history of liver disease, including chronic active hepatitis.** Patients with liver disease including chronic hepatitis B or C, who are treated with combination antiretrovirals, have a higher risk of severe and potentially life-threatening liver problems. Your doctor may conduct blood tests in order to check how well your liver is working or may switch you to another medicine. **If you have severe liver disease, do not take Atripla** (see earlier in section 2, *Do not take Atripla).*

  If you have hepatitis B infection, your doctor will carefully consider the best treatment regimen for you. Tenofovir disoproxil and emtricitabine, two of the active substances in Atripla, show some activity against hepatitis B virus although emtricitabine is not approved for the treatment of hepatitis B infection. Symptoms of your hepatitis may become worse after discontinuation of Atripla. Your doctor may then conduct blood tests at regular intervals in order to check how well your liver is working (see section 3, *If you stop taking Atripla).*

- Independent of a history of liver disease, your doctor will consider regular blood tests to check how your liver is working.

- **if you are over 65.** Insufficient numbers of patients over 65 years of age have been studied. If you are over 65 years of age and are prescribed Atripla, your doctor will monitor you carefully.

- **Once you start taking Atripla, look out for:**

  - **signs of dizziness, difficulty sleeping, drowsiness, difficulty concentrating or abnormal dreaming.** These side effects may start in the first 1 or 2 days of treatment and usually go away after the first 2 to 4 weeks.

  - **any signs of skin rash.** Rashes may be caused by Atripla. If you see any signs of a severe rash with blistering or fever, stop taking Atripla and tell your doctor at once. If you had a rash while taking another NNRTI, you may be at higher risk of getting a rash with Atripla.

  - **any signs of inflammation or infection.** In some patients with advanced HIV infection (AIDS) and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please tell your doctor at once.

    In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet

and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.

- **bone problems**. Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index, among others, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms please inform your doctor.

  Bone problems (sometimes resulting in fractures) may also occur due to damage to kidney tubule cells (see section 4, *Possible side effects*).

Children and adolescents

- **Do not give Atripla to children and adolescents** under 18 years of age. The use of Atripla in children and adolescents has not been studied.

Other medicines and Atripla

You must not take Atripla with certain medicines. These are listed under *Do not take Atripla,* at the start of section 2. They include some common medicines and some herbal preparations (including St. John's wort) which can cause serious interactions.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Also, Atripla should not be taken with any other medicines that contain efavirenz (unless recommended by your doctor), emtricitabine, tenofovir disoproxil, tenofovir alafenamide, or lamivudine or adefovir dipivoxil.

Tell your doctor if you are taking other medicines which may damage your kidneys. Some examples include:
- aminoglycosides, vancomycin (medicines for bacterial infections)
- foscarnet, ganciclovir, cidofovir (medicines for viral infections)
- amphotericin B, pentamidine (medicines for fungal infections)
- interleukin-2 (to treat cancer)
- non-steroidal anti-inflammatory drugs (NSAIDs, to relieve bone or muscle pains)

Atripla may interact with other medicines, including herbal preparations such as Ginkgo biloba extracts. As a result, the amounts of Atripla or other medicines in your blood may be affected. This may stop your medicines from working properly, or may make any side effects worse. In some cases, your doctor may need to adjust your dose or check your blood levels. **It is important to tell your doctor or pharmacist if you are taking any of the following:**

- **Medicines containing didanosine (for HIV infection):** Taking Atripla with other antiviral medicines that contain didanosine can raise the levels of didanosine in your blood and may reduce CD4 cell counts. Inflammation of the pancreas and lactic acidosis (excess lactic acid in the blood), which sometimes caused death, have been reported rarely when medicines containing tenofovir disoproxil and didanosine were taken together. Your doctor will carefully consider whether to treat you with medicines containing tenofovir and didanosine.
- **Other medicines used for HIV infection:** The following protease inhibitors: darunavir, indinavir, lopinavir/ritonavir, ritonavir, or ritonavir boosted atazanavir or saquinavir. Your doctor may consider giving you an alternative medicine or changing the dose of the protease inhibitors. Also, tell your doctor if you are taking maraviroc.

- **Medicines used to treat infection with the hepatitis C virus:** elbasvir/grazoprevir, glecaprevir/pibrentasvir, sofosbuvir/velpatasvir, sofosbuvir/velpatasvir/voxilaprevir.
- **Medicines used to lower blood fats (also called statins):** Atorvastatin, pravastatin, simvastatin. Atripla can reduce the amount of statins in your blood. Your doctor will check your cholesterol levels and will consider changing the dose of your statin, if needed.
- **Medicines used to treat convulsions/seizures (anticonvulsants):** Carbamazepine, phenytoin, phenobarbital. Atripla can reduce the amount of the anticonvulsant in your blood. Carbamazepine can reduce the amount of efavirenz, one of the components of Atripla, in your blood. Your doctor may need to consider giving you a different anticonvulsant.
- **Medicines used to treat bacterial infections,** including tuberculosis and AIDS-related mycobacterium avium complex: Clarithromycin, rifabutin, rifampicin. Your doctor may need to consider changing your dose or giving you an alternative antibiotic. In addition, your doctor may consider giving you an additional dose of efavirenz to treat your HIV infection.
- **Medicines used to treat fungal infections (antifungals):** Itraconazole or posaconazole. Atripla can reduce the amount of itraconazole or posaconazole in your blood. Your doctor may need to consider giving you a different antifungal.
- **Medicines used to treat malaria:** Atovaquone/proguanil or artemether/lumefantrine. Atripla may reduce the amount of atovaquone/proguanil or artemether/lumefantrine in your blood.
- **Hormonal contraceptive, such as birth control pills, an injected contraceptive (for example, Depo-Provera), or a contraceptive implant (for example, Implanon):** You must also use a reliable barrier method of contraception (see *Pregnancy and breast-feeding*). Atripla may make hormonal contraceptives less likely to work. Pregnancies have occurred in women taking efavirenz, a component of Atripla, while using a contraceptive implant, although it has not been established that the efavirenz therapy caused the contraceptive to fail.
- **Sertraline,** a medicine used to treat depression, as your doctor may need to change your dose of sertraline.
- **Bupropion**, a medicine used to treat depression or to help you stop smoking, as your doctor may need to change your dose of bupropion.
- **Diltiazem or similar medicines (called calcium channel blockers):** When you start taking Atripla, your doctor may need to adjust your dose of the calcium channel blocker.
- **Medicines used to prevent organ transplant rejection (also called immunosuppressants)**, such as cyclosporine, sirolimus or tacrolimus. When you start or stop taking Atripla your doctor will closely monitor your plasma levels of the immunosuppressant and may need to adjust its dose.
- **Warfarin or acenocoumarol** (medicines used to reduce clotting of the blood): Your doctor may need to adjust your dose of warfarin or acenocoumarol.
- **Ginkgo biloba extracts** (herbal preparation).

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Women should not get pregnant during treatment with Atripla and for 12 weeks thereafter. Your doctor may require you to take a pregnancy test to ensure you are not pregnant before starting treatment with Atripla.

If you could get pregnant while receiving Atripla, you need to use a reliable form of barrier contraception (for example, a condom) with other methods of contraception including oral (pill) or other hormonal contraceptives (for example, implants, injection). Efavirenz, one of the active components of Atripla, may remain in your blood for a time after therapy is stopped. Therefore, you should continue to use contraceptive measures, as above, for 12 weeks after you stop taking Atripla.

Tell your doctor immediately if you are pregnant or intend to become pregnant. If you are pregnant, you should take Atripla only if you and your doctor decide it is clearly needed.

Serious birth defects have been seen in unborn animals and in the babies of women treated with efavirenz during pregnancy.

Ask your doctor or pharmacist for advice before taking any medicine.

If you have taken Atripla during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child. In children whose mothers took NRTIs during pregnancy, the benefit from the protection against HIV outweighed the risk of side effects.

Do not breast-feed during treatment with Atripla. Both HIV and the ingredients of Atripla may pass through breast milk and cause serious harm to your baby.

Driving and using machines

Atripla may cause dizziness, impaired concentration and drowsiness. If you are affected, do not drive and do not use any tools or machines.

Atripla contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Atripla

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:
One tablet taken each day by mouth. Atripla should be taken on an empty stomach (commonly defined as 1 hour before or 2 hours after a meal) preferably at bedtime. This may make some side effects (for example, dizziness, drowsiness) less troublesome. Swallow Atripla whole with water.

Atripla must be taken every day.

If your doctor decides to stop one of the components of Atripla, you may be given efavirenz, emtricitabine and/or tenofovir disoproxil separately or with other medicines for the treatment of your HIV infection.

If you take more Atripla than you should

If you accidentally take too many Atripla tablets you may be at increased risk of experiencing possible side effects with this medicine (see section 4, *Possible side effects*). Contact your doctor or nearest emergency department for advice. Keep the tablet bottle with you so that you can easily describe what you have taken.

If you forget to take Atripla

It is important not to miss a dose of Atripla.

If you do miss a dose of Atripla within 12 hours of when it is usually taken, take it as soon as you can, and then take your next dose at its regular time.

If it is almost time (less than 12 hours) for your next dose anyway, do not take the missed dose. Wait and take the next dose at the regular time. Do not take a double dose to make up for a forgotten tablet.

If you throw up the tablet (within 1 hour after taking Atripla), you should take another tablet. Do not wait until your next dose is due. You do not need to take another tablet if you were sick more than 1 hour after taking Atripla.

If you stop taking Atripla

Don't stop taking Atripla without talking to your doctor. Stopping Atripla can seriously affect your response to future treatment. If Atripla is stopped, speak to your doctor before you restart taking Atripla tablets. Your doctor may consider giving you the components of Atripla separately if you are having problems or need your dose adjusted.

When your supply of Atripla starts to run low, get more from your doctor or pharmacist. This is very important because the amount of virus may start to increase if the medicine is stopped for even a short time. The virus may then become harder to treat.

If you have both HIV infection and hepatitis B, it is especially important not to stop your Atripla treatment without talking to your doctor first. Some patients have had blood tests or symptoms indicating that their hepatitis has got worse after stopping emtricitabine or tenofovir disoproxil (two of the three components of Atripla). If Atripla is stopped your doctor may recommend that you resume hepatitis B treatment. You may require blood tests to check how your liver is working for 4 months after stopping treatment. In some patients with advanced liver disease or cirrhosis, stopping treatment is not recommended as this may lead to worsening of your hepatitis, which may be life-threatening.

→Tell your doctor immediately about new or unusual symptoms after you stop treatment, particularly symptoms you associate with hepatitis B infection.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible serious side effects: tell your doctor immediately

- **Lactic acidosis** (excess lactic acid in the blood) is a **rare** (may affect up to 1 in every 1,000 patients) but serious side effect that can be fatal. The following side effects may be signs of lactic acidosis:
  - deep rapid breathing
  - drowsiness
  - feeling sick (nausea), being sick (vomiting) and stomach pain.

→If you think you may have lactic acidosis, contact your doctor immediately.

Other possible serious side effects

The following side effects are **uncommon** (these may affect up to 1 in every 100 patients):

- allergic reaction (hypersensitivity) that may cause severe skin reactions (Stevens-Johnson syndrome, erythema multiforme, see section 2)
- swelling of the face, lips, tongue or throat
- angry behaviour, suicidal thoughts, strange thoughts, paranoia, unable to think clearly, mood being affected, seeing or hearing things that are not really there (hallucinations), suicide

attempts, personality change (psychosis), catatonia (a condition in which the patient is rendered motionless and speechless for a period).
- pain in the abdomen (stomach), caused by inflammation of the pancreas
- forgetfulness, confusion, fitting (seizures), incoherent speech, tremor (shaking)
- yellow skin or eyes, itching, or pain in the abdomen (stomach) caused by inflammation of the liver
- damage to kidney tubules

Psychiatric side effects in addition to those listed above include delusions (false beliefs), neurosis. Some patients have committed suicide. These problems tend to occur more often in those who have a history of mental illness. Always notify your doctor immediately if you have these symptoms.

Side effects to the liver: If you are also infected with hepatitis B virus, you may experience a worsening of hepatitis after discontinuation of treatment (see section 3).

The following side effects are **rare** (these may affect up to 1 in every 1,000 patients):

- liver failure, in some cases leading to death or liver transplant. Most cases occurred in patients who already had liver disease, but there have been a few reports in patients without any existing liver disease
- inflammation of the kidney, passing a lot of urine and feeling thirsty
- back pain caused by kidney problems, including kidney failure. Your doctor may do blood tests to see if your kidneys are working properly
- softening of the bones (with bone pain and sometimes resulting in fractures) which may occur due to damage to the kidney tubule cells
- fatty liver

→If you think that you may have any of these serious side effects, talk to your doctor.

Most frequent side effects

The following side effects are **very common** (these may affect more than 1 in 10 patients)

- dizziness, headache, diarrhoea, feeling sick (nausea), being sick (vomiting)
- rashes (including red spots or blotches sometimes with blistering and swelling of the skin), which may be allergic reactions
- feeling weak

Tests may also show:
- decreases in phosphate levels in the blood
- increased levels of creatine kinase in the blood that may result in muscle pain and weakness

Other possible side effects

The following side effects are **common** (these may affect up to 1 in 10 patients)

- allergic reactions
- disturbances of coordination and balance
- feeling worried or depressed
- difficulty sleeping, abnormal dreams, difficulty concentrating, drowsiness
- pain, stomach pain
- problems with digestion resulting in discomfort after meals, feeling bloated, wind (flatulence)
- loss of appetite
- tiredness
- itching

- changes in skin colour including darkening of the skin in patches often starting on hands and soles of feet

Tests may also show:
- low white blood cell count (a reduced white blood cell count can make you more prone to infection)
- liver and pancreas problems
- increased fatty acids (triglycerides), bilirubin or sugar levels in the blood

The following side effects are **uncommon** (these may affect up to 1 in every 100 patients):

- breakdown of muscle, muscle pain or weakness
- anaemia (low red blood cell count)
- a feeling of spinning or tilting (vertigo), whistling, ringing or other persistent noise in the ears
- blurred vision
- chills
- breast enlargement in males
- decreased sexual drive
- flushing
- dry mouth
- increased appetite

Tests may also show:
- decreases in potassium in the blood
- increases in creatinine in the blood
- proteins in urine
- increased cholesterol in the blood

The breakdown of muscle, softening of the bones (with bone pain and sometimes resulting in fractures), muscle pain, muscle weakness and decreases in potassium or phosphate in the blood may occur due to damage to kidney tubule cells.

The following side effects are **rare** (these may affect up to 1 in every 1,000 patients)

- itchy rash to the skin caused by a reaction to sunlight

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Atripla

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the bottle and carton after {EXP}. The expiry date refers to the last day of that month.

Store in the original package in order to protect from moisture. Keep the bottle tightly closed.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Atripla contains

- The active substances are efavirenz, emtricitabine and tenofovir disoproxil. Each Atripla film-coated tablet contains 600 mg of efavirenz, 200 mg of emtricitabine and 245 mg of tenofovir disoproxil (as fumarate).
- The other ingredients in the tablet are croscarmellose sodium, hyprolose, magnesium stearate, microcrystalline cellulose, sodium laurilsulfate. Refer to section 2 "Atripla contains sodium".
- The other ingredients in the tablet film coating are iron oxide black, iron oxide red, macrogol 3350, poly(vinyl alcohol), talc, titanium dioxide.

What Atripla looks like and contents of the pack

Atripla film-coated tablets are pink, capsule shaped tablets, engraved on one side with the number "123" and plain on the other side. Atripla comes in bottles of 30 tablets (with a silica gel sachet that must be kept in the bottle to help protect your tablets). The silica gel desiccant is contained in a separate sachet and should not be swallowed.

The following pack sizes are available: outer cartons containing 1 bottle of 30 film-coated tablets and 90 (3 bottles of 30) film-coated tablets. Not all pack sizes may be marketed.

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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.