

Efavirenz/Lamivudine/Tenofovir
Disoproxil Fumarate
600 mg/300 mg /300 mg, Tablets
(Macleods Pharmaceuticals Ltd), HA611

WHOPAR part 3

July 2016
Section 6 updated : October 2019

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Efavirenz/Lamivudine/Tenofovir disoproxil fumarate 600 mg / 300 mg/300 mg Tablets

Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300mg/300mg Tablets*

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets is and what it is used for
2. What you need to know before you take Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets
3. How to take Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets
4. Possible side effects
5. How to store Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets
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1. WHAT EFAVIRENZ/LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE 600MG/300MG/300MG TABLETS IS AND WHAT IT IS USED FOR

Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets is a combination of three antiviral medicines used to treat Human Immunodeficiency Virus (HIV) infection in adults and adolescents. Antiviral medicines used for HIV infection are known as *antiretrovirals*.

Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets contains the active substances:

- efavirenz, a non-nucleoside reverse transcriptase inhibitor
- lamivudine, a nucleoside reverse transcriptase inhibitor
- tenofovir disoproxil fumarate, a nucleotide reverse transcriptase inhibitor

These substances block an enzyme (reverse transcriptase) that is used by HIV for making copies of itself. By doing so, they prevent the reproduction of the virus.

* Trade names are not prequalified by WHO. This is the National Medicines Regulatory Authority's responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

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This medicine is not a cure for HIV infection. While taking Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets you may still develop infections or other illnesses associated with HIV infection.

2. BEFORE YOU TAKE EFAVIRENZ/LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE 600 MG/300 MG/300 MG TABLETS

Do not take Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets if you:

- are allergic (hypersensitive) to efavirenz, lamivudine, tenofovir disoproxil fumarate or any of the other ingredients of Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets listed at the end of this leaflet (section 6).
- are currently taking any of the following medicines:
 - **astemizole** or **terfenadine** (used to treat hay fever or other allergies)
 - **bepidril** (used to treat heart disease)
 - **cisapride** (used to treat heartburn)
 - **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** (used to treat certain mental conditions)
 - **voriconazole** (a drug used against fungal infections)
 - **dasabuvir + ombitasvir/paritaprevir/ritonavir** (a combination of medicines used to treat infection with hepatitis C virus)
 - **St. John's wort** (*Hypericum perforatum*, a herbal remedy used for depression and anxiety).

If this applies to you, tell your health care provider immediately. Taking these medicines with Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets could cause serious or life-threatening side effects or stop these medicines from working properly.

Take special care with Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets:

Talk to your health care provider before taking Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets.

You will need to take this medicine every day. It helps to control your condition, but it is not a cure for HIV infection. You may continue to develop other infections and other illnesses associated with HIV disease. You can still pass on HIV to others through sexual contact or contamination with blood when taking this medicine. You must continue to take precautions to avoid this.

You should keep in regular contact with your health care provider. Do not stop taking your medicine without first talking to your health care provider.

Tell your health care provider if you:

- **are taking other medicines** that contain efavirenz, lamivudine, tenofovir disoproxil, or emtricitabine or adefovir dipivoxil. Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets should not be taken with any of these medicines.
- **have or have had kidney disease**, or if tests have shown problems with your kidneys. This medicine may affect your kidneys. Before starting this medicine you may need blood tests to check how well your kidneys are working. Blood tests may also be required during treatment to check the health of your kidneys.
- **have a history of mental illness**, including depression, or of substance or alcohol abuse. Tell your health care provider immediately if you feel depressed, have suicidal thoughts or have strange thoughts (see section 4, *Possible side effects*).

- **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 health care provider may need to check the level of anticonvulsant medicine in your blood to ensure that it is not affected while taking Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600mg/300mg/300mg Tablets.
- **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. If you have hepatitis B infection, your health care provider will carefully consider the best treatment regimen for you. Your health care provider may conduct blood tests to check how well your liver is working.

Once you start taking Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets, 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 Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets. If you see any signs of a severe rash with blistering or fever, stop taking this medicine and tell your health care provider at once.
- **any signs of inflammation or infection.** In some patients with advanced HIV infection (AIDS) and a history of AIDS-associated (opportunistic) infection, signs and symptoms of inflammation from such 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 health care provider at once.

In addition, 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. These 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, irregular heartbeats, trembling or shaking, or hyperactivity, please inform your health care provider at once.

- **any signs of 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 duration of antiretroviral therapy, use of a corticosteroid such as dexamethasone or prednisolone, alcohol consumption, severe suppression of the immune system, and being overweight 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, tell your health care provider.

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

The growth of bone could be affected when adolescents that are not fully grown use Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets. If you are an adolescent, your health care provider may check your growth and may take precautionary measures.

Taking other medicines and Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets

You must not take Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets with certain medicines. Tell your health care provider immediately if you are taking **astemizole** or **terfenadine** (used to treat hay fever or other allergies), **bepidil** (used to treat heart disease), **cisapride** (used to treat heartburn), **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** (used to treat certain mental conditions), **voriconazole** (a drug used against fungal infections), **dasabuvir + ombitasvir/paritaprevir/ritonavir** (a combination of medicines used to treat infection with hepatitis C virus), **St. John's wort** (*Hypericum perforatum*, a herbal remedy used for depression and anxiety) (see section: *do not take Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600mg/300 mg/300 mg Tablets if you*).

Tell your health care provider if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Also, Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets should not be taken with other medicines that contain efavirenz (unless recommended by your health care provider), lamivudine, tenofovir disoproxil fumarate, or emtricitabine or adfovir dipivoxil.

Tell your health care provider if you are taking other medicines that may damage your kidneys. These include:

- aminoglycosides or vancomycin (medicines for bacterial infections)
- amphotericin B or pentamidine (medicines for fungal infections)
- foscarnet, ganciclovir, or cidofovir (medicines for viral infections)
- tacrolimus (for suppression of the immune system)
- interleukin-2 (used to treat cancer)
- non-steroidal anti-inflammatory drugs (NSAIDs, to relieve bone or muscle pains)

Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets may interact with other medicines, including herbal preparations such as Ginkgo biloba extracts. As a result, the amounts of Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets 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 health care provider may need to adjust your dose or check your blood levels. **It is important to tell your health care provider if you are taking any of the following:**

- **Medicines containing didanosine (for HIV infection):** Taking Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets with medicines that contain didanosine can raise the levels of didanosine in your blood. Rarely, inflammation of the pancreas and lactic acidosis (excess lactic acid in the blood), which sometimes caused death, has been reported when medicines containing tenofovir disoproxil fumarate and didanosine were taken together. Combining tenofovir with didanosine can also reduce the effects of antiretroviral therapy.

Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets may also interact with the following medicines and may make any side effects worse or may impact on the either agent's efficacy:

- **amprenavir, atazanavir, darunavir, etravirine, fosamprenavir, indinavir, lopinavir, maraviroc, nevirapine, ritonavir, saquinavir and tipranavir** (medicines used to treat HIV infection)

- **boceprevir, daclatasvir, simeprevir and telaprevir** (used to treat infection with hepatitis C virus)
- **methadone, buprenorphine** (medicines used for severe pain or opiate addiction)
- **clarithromycin, rifabutin and rifampicin** (medicines used to treat bacterial infections and tuberculosis)
- **atorvastatin, pravastatin, or simvastatin** (medicines used to lower blood fats, also called statins)
- **hormonal contraceptives** such as birth control pills, an injected contraceptive or a contraceptive implant. Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets may make hormonal contraceptives less likely to work. You must, therefore, also use a reliable barrier method of contraception (e.g. condoms), if you are taking this medicine.
- **itraconazole, posaconazole** (medicines used to treat fungal infections)
- **lumefantrine/artesunate, atovaquone/proguanil, amodiaquine/artesunate, quinine, halofantrine, artemisinin** (medicines used to treat malaria)
- **carbamazepine, phenytoin** (medicines used to treat convulsions/seizures (epilepsy))
- **diltiazem, verapamil, felodipine, nifedipine, nicardipine** (medicines called calcium channel blockers, used to treat high blood pressure and conditions related to the heart)
- **tacrolimus, cyclosporine, sirolimus** (medicines used to prevent organ transplant rejection, also called immunosuppressants)
- **sertraline** (medicine used to treat depression)
- **warfarin and acenocoumarol** (medicines used to reduce clotting of the blood)
- **bupropion** (medicine used for smoking cessation)

Pregnancy and breast-feeding

Pregnancy

Tell your health care provider if you are pregnant or trying to become pregnant. Your health care provider can explain the risks and benefits of your therapy to you and your child.

Breastfeeding

If you are interested in breastfeeding your baby, you should discuss the risks and benefits with your healthcare provider.

Driving and using machines

Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets may cause dizziness, impaired concentration, and drowsiness. If you experience these symptoms, do not drive and do not use any tools or machines.

Important information about some of the ingredients of Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets

This medicine contains sodium. If you are on a controlled sodium diet, please contact your health care provider before taking this medicine.

If you have been told by your child's health care provider that your child has intolerance to some sugars, contact your child's health care provider before taking this medicinal product

3. HOW TO TAKE EFAVIRENZ/LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE 600MG/300MG/300MG TABLETS.

Always take Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets exactly as your health care provider. Check with your health care provider if you are not sure.

Always take the dose recommended by your health care provider. Do not change the dose unless your health care provider tells you to.

The recommended dose is:

One tablet taken each day by mouth. Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets should be taken on an empty stomach (1 hour before or 2 hours after a meal). It may help to take the tablet at bedtime, as this can make some side effects (for example, dizziness, drowsiness) less troublesome. The tablet should be taken with water and swallowed whole.

Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets must be taken every day.

Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets should not be used by children under 10 years of age or weighing less than 35 kg.

If your health care provider decides to stop, or change the dose of, one of the components of Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets, you may be given efavirenz, lamivudine and/or tenofovir separately or with other medicines for the treatment of HIV infection.

If you take more Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets than you should:

If you accidentally take too many Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets, you may be at increased risk of experiencing possible side effects with this medicine (see section 4, Possible side effects). Contact your health care provider or the nearest emergency department for advice. Take the tablet container with you so that you can easily describe what you have taken.

If you forget to take Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets:

It is important not to miss a dose.

If you do miss a dose 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 within 1 hour of taking Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets, you should take another tablet. Do not wait until your next dose is due. You do not need to take another tablet if you threw up more than an hour after taking Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets.

If you stop taking Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets:

Don't stop taking this medicine without talking to your health care provider. Stopping this medicine can seriously affect your response to future treatment. If Efavirenz/Lamivudine/Tenofovir

Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets is stopped, speak to your health care provider before you restart taking these tablets. Your health care provider may consider giving you the components of Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets separately if you are having problems or need your dose adjusted.

When your supply of Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate

600 mg/300 mg/300 mg Tablets starts to run low, get more from your health care provider. 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 Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets treatment without talking to your health care provider first. Some patients have had blood tests or symptoms indicating that their hepatitis got worse after stopping treatment. Your health care provider may recommend that you resume hepatitis B treatment if you stop Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets 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 health care provider 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 product, ask your health care provider.

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 health care provider will test for these changes.

Like all medicines, Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets can cause side effects, although not everybody gets them.

Possible serious side effects:

Lactic acidosis (excess lactic acid in the blood) is a **rare**, but serious side effect that can be life-threatening. If you get any of the following symptoms, **tell your health care provider immediately**:

- deep rapid breathing
- drowsiness
- feeling sick (nausea), being sick (vomiting) and stomach pain.

Other potentially serious side effects:

If you think that you may have any of these serious side effects, talk to your health care provider.

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)
- 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

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 health care provider 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 stopping treatment (see section 3 *How to take Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets*).

The following side effects are **rare** (these may affect up to 1 in every 1000 patients):

- back pain caused by kidney problems, including kidney failure. Your health care provider may do blood tests to see if your kidneys are working properly.
- inflammation of the kidney, passing a lot of urine and feeling thirsty, damage to kidney tubule cells
- fatty liver
- 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.
- softening of the bones (with bone pain and sometimes resulting in fractures)

Most frequent side effects

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

- dizziness, 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

Other possible side effects

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

- stomach pain
- difficulty sleeping, abnormal dreams, difficulty concentrating, drowsiness
- feeling worried or depressed
- problems with digestion resulting in discomfort after meals, feeling bloated, wind (flatulence)
- loss of appetite
- tiredness
- itching
- hair loss
- disturbances of coordination and balance
- headache
- cough
- irritated or runny nose
- fever (high temperature)

- general feeling of being unwell

Tests may also show:

- increased fatty acids (triglycerides) or sugar levels in the blood
- liver and pancreas problems

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

- blurred vision
- a feeling of spinning or tilting (vertigo), whistling, ringing or other persistent noise in the ears
- flushing
- breast enlargement in males
- breakdown of muscle, muscle pain or weakness

Tests may also show:

- low white blood cell count that help defend against infections and low red blood cell count (anaemia)
- low red blood cell count (thrombocytes) that help to stop bleeding
- increased cholesterol in the blood
- decreases in potassium in the blood
- increases in creatinine in the blood
- proteins in urine

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

The following side effects are **very rare** (these may affect up to 1 user in every 10,000 patients)

- a failure of the bone marrow to produce new red blood cells (pure red cell aplasia)
- tingling or numbness of the arms, legs, hands or feet

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

5. HOW TO STORE EFAVIRENZ/LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARATE 600 MG/300 MG/300 MG TABLETS

Keep out of the reach and sight of children.

Do not use Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets 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 below 30°C, in a dry place, protected from light.

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.

6. FURTHER INFORMATION

What Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets contain

The active ingredients are 600 mg efavirenz, 300 mg lamivudine, 300 mg tenofovir disoproxil fumarate 300 mg (equivalent to 245 mg of tenofovir disoproxil or 136 mg of tenofovir).

The other ingredients are: Croscarmellose sodium, Hydroxypropylcellulose, Lactose monohydrate, Magnesium stearate, Microcrystalline cellulose, Poloxamer, Pregelatinized starch, Sodium lauryl sulfate, and for the film coat: Lactose monohydrate, Hypromellose, Titanium dioxide, Triacetin.

“This product contains Lactose”

What Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets look like and contents of the pack

Efavirenz/Lamivudine/Tenofovir Disoproxil Fumarate 600 mg/300 mg/300 mg Tablets are white to off-white, capsule shaped, film coated tablets, debossed with “M9” on one side and plain on other side.

30 Tablets packed in 120 cc Heavy weight HDPE container with 38 mm continuous thread PP closure, 2 sachets each of 3 gm silica gel and with pack insert finally induction sealed.

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For any information about this medicinal product, please contact the supplier.

Efavirenz/Lamivudine/Tenofovir
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Detailed information on this medicine is available on the World Health Organization (WHO) web site: <https://extranet.who.int/prequal/>.