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Each film coated tablet contains 600 mg of efavirenz, 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate, which is equivalent to 245 mg of tenofovir disoproxil.

USUAL DOSAGE: See package insert for dosage and administration.

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].

Keep container tightly closed. Dispense only in original container.

U.S. Contact Number:
1-866-495-1995

NDC 68554-5036-0

Efavirenz, Emtricitabine and Tenofovir Disoproxil Fumarate Tablets

600 mg/200 mg/300 mg

Note to pharmacist: Do not cover ALERT box with pharmacy label. Dispense the patient information leaflet with drug product.

ALERT: Find out about medicines that should NOT be taken with efavirenz, emtricitabine and tenofovir disoproxil fumarate.

Rx only
30 Tablets



Mfg. Lic. No.: 50/MN/AP/2009/F/R

UNARNISH AREA

Manufactured by:
HETERO™
HETERO LABS LIMITED
Unit V, Polepally, Jadcherla,
Mahaboob Nagar - 509 301, India.

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Size: 120 x 40 mm

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Patient Information

Efavirenz, Emtricitabine and Tenofovir disoproxil fumarate Tablets

ALERT: Find out about medicines that should NOT be taken with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.

Please also read the section **"MEDICINES YOU SHOULD NOT TAKE WITH EFAVIRENZ, EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS."**

Generic name: efavirenz, emtricitabine and tenofovir disoproxil fumarate (eff-ah-VYE-renz, em-trah-SYE-tah-beenand teh-NOE-foh-veer dye soe PROX il FYOU marate)

Read the Patient Information that comes with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets 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 efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets. **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 efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.

What is the most important information I should know about efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets?

- **Some people who have taken medicine like efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets (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 efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets 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 efavirenz, emtricitabine and tenofovir disoproxil fumarate, for a long time.
- **If you also have hepatitis B Virus (HBV) infection and you stop taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets 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 efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets need close medical follow-up for several months, including medical exams and blood tests to check for hepatitis that could be getting worse. Efavirenz, Emtricitabine and Tenofovir disoproxil fumarate tablets are not approved for the treatment of HBV, so you must discuss your HBV therapy with your healthcare provider.

What are efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets?

Efavirenz, Emtricitabine and Tenofovir disoproxil fumarate tablets 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®. Efavirenz, Emtricitabine and Tenofovir disoproxil fumarate tablets can be used alone as a complete regimen, or in combination with other anti-HIV-1 medicines to treat people with HIV-1 infection. Efavirenz, Emtricitabine and Tenofovir disoproxil fumarate tablets are for adults and children 12 years of age and older who weigh at least 40 kg (at least 88 lbs). Efavirenz, Emtricitabine and Tenofovir disoproxil fumarate tablets is not recommended for children younger than 12 years of age. Efavirenz, Emtricitabine and Tenofovir disoproxil fumarate tablets 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.

Efavirenz, Emtricitabine and Tenofovir disoproxil fumarate tablets helps block HIV-1 reverse transcriptase, a viral chemical in your body (enzyme) that is needed for HIV-1 to multiply. Efavirenz, Emtricitabine and Tenofovir disoproxil fumarate tablets lowers the amount of HIV-1 in the blood (viral load). Efavirenz, Emtricitabine and Tenofovir disoproxil fumarate tablets 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 efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets cure HIV-1 or AIDS?

Efavirenz, Emtricitabine and Tenofovir disoproxil fumarate tablets 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 efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.

Who should not take efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets?

Together with your healthcare provider, you need to decide whether efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets are right for you.

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

What should I tell my healthcare provider before taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets?

Tell your healthcare provider if you:

- **Are pregnant or planning to become pregnant** (see "What should I avoid while taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets?").
- **Are breastfeeding** (see "What should I avoid while taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets?").
- **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 efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets or may switch you to another medicine.
- **Have ever had mental illness or are using drugs or alcohol.**
- **Have ever had seizures or are taking medicine for seizures.**

What important information should I know about taking other medicines with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets?

Efavirenz, Emtricitabine and Tenofovir disoproxil fumarate tablets may change the effect of other medicines, including the ones for HIV-1, 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 efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets. 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 EFAVIRENZ, EMTRICITABINE AND TENOFOVIR DISOPROXIL FUMARATE TABLETS

- Efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets also should not be used with Combivir (lamivudine/zidovudine), COMPLERA®, EMTRIVA, Eпивir-HBV (lamivudine), Epizcom (abacavir sulfate/lamivudine), STRIBILD®, Trizivir (abacavir sulfate/lamivudine/zidovudine), TRUVADA, or VIREAD. Efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets also should not be used with SUSTIVA unless recommended by your healthcare provider.
- Vfend (voriconazole) should not be taken with efavirenz, emtricitabine and tenofovir disoproxil fumarate since it may lose its effect or may increase the chance of having side effects from efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.
- Efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets should not be used with HEPSERA® (adefovir dipivoxil).

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

- Fortovase, Invirase (saquinavir), Biaxin (clarithromycin), Noxafil (Posaconazole), Sporanox (itraconazole), or Olysio (simeprevir); **these medicines may need to be replaced with another medicine when taken with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets**.
- Calcium channel blockers such as Cardizem or Tiazac (diltiazem), Covera HS or Isoptin (verapamil) and others; Crixivan (indinavir), Selzentry (maraviroc); the immunosuppressant medicines cyclosporine (Gengraf, Neoral, Sandimmune, and others), Prograf (tacrolimus), or Rapamune (sirolimus); Methadone; Mycobutin (rifabutin); Rifampin; cholesterol-lowering medicines such as Lipitor (atorvastatin), Pravachol (pravastatin sodium), and Zocor (simvastatin); or the anti-depressant medications bupropion (Wellbutrin, Wellbutrin SR, Wellbutrin XL, and Zyban) or Zoloft (sertraline); **dose changes may be needed when these drugs are taken with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.**
- Videx, Videx EC (didanosine); tenofovir DF (a component of efavirenz, emtricitabine and tenofovir disoproxil fumarate) tablets 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 efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets and didanosine together. Also, the dose of didanosine may need to be changed.
- Reyataz (atazanavir sulfate), Prezista (darunavir) with Norvir (ritonavir), Kaletra (lopinavir/ritonavir) or Harvoni (ledipasvir/sofosbuvir); these medicines may increase the amount of tenofovir DF (a component of Efavirenz, Emtricitabine and Tenofovir disoproxil fumarate tablets) in your blood, which could result in more side effects. Reyataz is not recommended with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets. **You may need to be monitored more carefully** if you are taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablet, Prezista, and Norvir together, or if you are taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets and Kaletra together. The dose of Kaletra should be increased when taken with efavirenz.
- Medicine for seizures [for example, Dilantin (phenytoin), Tegretol (carbamazepine), or phenobarbital]; your healthcare provider may want to switch you to another medicine or check drug levels in your blood from time to time.

These are not all the medicines that may cause problems if you take efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.

Be sure to tell your healthcare provider about all medicines that you take.

Keep a complete list of all the prescription and nonprescription 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.

How should I take efavirenz, emtricitabine and tenofovir disoproxil fumarate tablet?

- Take the exact amount of efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets your healthcare provider prescribes. Never change the dose on your own. Do not stop this medicine unless your healthcare provider tells you to stop.
- You should take efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets on an empty stomach.
- Swallow efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets with water.
- Taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets at bedtime may make some side effects less bothersome.

- Do not miss a dose of efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets. If you forget to take efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets, 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 efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets, contact your local poison control center 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 efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets 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 efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets and become harder to treat.
- Your healthcare provider may want to do blood tests to check for certain side effects while you take efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.

What should I avoid while taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets?

- **Women should not become pregnant while taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets and for 12 weeks after stopping it.** Serious birth defects have been seen in the babies of animals and women treated with efavirenz (a component of efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets) 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 efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets 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. Efavirenz, a component of efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets, may remain in your blood for a time after therapy is stopped. Therefore, you should continue to use contraceptive measures for 12 weeks after you stop taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.
- **Do not breastfeed if you are taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.** Some of the medicines in efavirenz, emtricitabine and tenofovir disoproxil fumarate can be passed to your baby in your breast milk. We do not know whether it could harm your baby. Also, mothers with HIV-1 should not breastfeed because HIV-1 can be passed to the baby in the breast milk. Talk with your healthcare provider if you are breastfeeding. You should stop breastfeeding or may need to use a different medicine.
- Taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets with alcohol or other medicines causing similar side effects as efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets, such as drowsiness, may increase those side effects.
- Do not take any other medicines, including prescription and nonprescription medicines and herbal products, without checking with your healthcare provider.
- Avoid doing things that can spread HIV-1 to others.
 - **Do not share needles or other injection equipment.**
 - **Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.**
 - **Do not have any kind of sex without protection.** Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

What are the possible side effects of efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets?

Efavirenz, Emtricitabine and Tenofovir disoproxil fumarate tablets may cause the following serious side effects:

- **Lactic acidosis** (buildup 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.** (See "What is the most important information I should know about emtricitabine and tenofovir disoproxil fumarate tablets?")
- **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 efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets?")
- **"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 efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets. Your healthcare provider will monitor your condition for several months after stopping efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets if you have both HIV-1 and HBV infection and may recommend treatment for your HBV. Efavirenz, Emtricitabine and Tenofovir disoproxil fumarate tablets are not approved for the treatment of hepatitis B virus infection. If you have advanced liver disease and stop treatment with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets, the "flare-up" of hepatitis B may cause your liver function to decline.
- **Serious psychiatric problems.** A small number of patients may experience severe depression, strange thoughts, or angry behavior while taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets. 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 efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.
- **Kidney problems** (including decline or failure of kidney function). 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. 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).** Laboratory tests show changes in the bones of patients treated with tenofovir DF, a component of efavirenz, emtricitabine and tenofovir disoproxil fumarate. Some HIV patients treated with tenofovir DF developed thinning of the bones (osteopenia) which could lead to fractures. 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. Additionally, bone pain and softening of the bone (which may contribute to fractures) may occur as a consequence of kidney problems.

Common side effects:

Patients may have dizziness, headache, trouble sleeping, drowsiness, trouble concentrating, and/or unusual dreams during treatment with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets. These side effects may be reduced if you take efavirenz, emtricitabine and tenofovir disoproxil fumarate at bedtime on an empty stomach. They also tend to go away after you have taken the medicine for a few weeks. If you have these common side effects, such as dizziness, it does not mean that you will also have serious psychiatric problems, such as severe depression, strange thoughts, or angry behavior. 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 efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets are used with alcohol or mood altering (street) drugs.

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

Rash may be 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. **Rash may be a serious problem in some children.** Tell your child's healthcare provider right away if you notice rash or any other side effects while your child is taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.

Other common side effects include tiredness, upset stomach, vomiting, gas, and diarrhea.

Other possible side effects with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets:

- Changes in body fat. Changes in body fat develop in some patients taking anti HIV-1 medicine. 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 discoloration (small spots or freckles) may also happen with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.
- 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. It is believed that these symptoms are due to an 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 inform your doctor immediately.
- 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.

Tell your healthcare provider or pharmacist if you notice any side effects while taking efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.

Contact your healthcare provider before stopping efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets because of side effects or for any other reason.

This is not a complete list of side effects possible with efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets. Ask your healthcare provider or pharmacist for a more complete list of side effects of efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets and all the medicines you will take.

How do I store efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets?

- **Keep efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets and all other medicines out of reach of children.**
- Store efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets at room temperature 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].
- Keep efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets in its original container and keep the container tightly closed.
- Do not keep medicine that is out of date or that you no longer need. If you throw away medicines you make sure that children will not find them.

General information about efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets:

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets for a condition for which it was not prescribed. Do not give efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets that is written for health professionals.

Do not use efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets if the seal over bottle opening is broken or missing.

What are the ingredients of efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets?

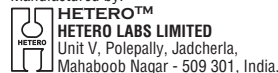
Active Ingredients: efavirenz, emtricitabine, and tenofovir disoproxil fumarate

Inactive Ingredients: croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose and sodium lauryl sulfate. The tablets are coated with opadry II pink containing black iron oxide, polyethylene glycol, polyvinyl alcohol, red iron oxide, talc and titanium dioxide.

April 2016

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Manufactured by:



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