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

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**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

**U.S.C. Code:**

3

**NDC:** 68554-5036-0

**Pantone Process Cyan C**  **Pantone 485 C**  **Black**

**Size:** 120 x 40 mm

**Pharma Code:** 2288

**Spec.:** Printed on 80 GSM Fasson fas print permanent (HITAC) of Avery Dennison with Aqua Varnish, 62 GSM release paper, in roll form with number printed on release paper.

**No of Colour:** 03

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**Manufactured by:**

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

**NDC 68554-5036-0**
Alert: Find out about medicines that should NOT be taken with etravirine, emtricitabine and tenofovir disoproxil fumarate tablets.

What should I tell my healthcare provider before taking etravirine, 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 etravirine, emtricitabine and tenofovir disoproxil fumarate tablets?”).
- Are breastfeeding (see “What should I avoid while taking etravirine, 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 etravirine, 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 emtricitabine and tenofovir disoproxil fumarate tablets?

- Etravirine, emtricitabine and tenofovir disoproxil fumarate tablets also should not be used with Comvir (lamivudine/abacavir), COMPLERA® (EMTRIVA, Epivir-300, Truvada, Atripla), or Isentress (raltegravir).
- Etravirine, emtricitabine and tenofovir disoproxil fumarate tablets also should not be used with SUSTIVA, norwith any antiretroviral drug regimen that contains delavirdine.
- Etravirine, emtricitabine and tenofovir disoproxil fumarate tablets should not be used with NUCIT®.
- Etravirine, emtricitabine and tenofovir disoproxil fumarate tablets should not be used with Viread (tenofovir).
- Etravirine, emtricitabine and tenofovir disoproxil fumarate tablets should not be used with Viread (tenofovir).
- Etravirine, emtricitabine and tenofovir disoproxil fumarate tablets should not be used with Viread (tenofovir).
- Etravirine, emtricitabine and tenofovir disoproxil fumarate tablets should not be used with Viread (tenofovir).
- Etravirine, emtricitabine and tenofovir disoproxil fumarate tablets should not be used with Viread (tenofovir).
• Do not miss a dose of etaviren, efavirenz, and tenofovir disoproxil fumarate tablets. If you forget to take efavirenz, etaviren, and tenofovir disoproxil fumarate tablets, take the missed dose right away. Do not double the next dose. Carry at least a 30 days supply. 

• Store the medication in a cool dry place. Do not put in the refrigerator. 

• Keep etaviren, efavirenz and tenofovir disoproxil fumarate tablets away from heat, sunlight, and humidity. 

• Do not store etaviren, efavirenz and tenofovir disoproxil fumarate tablets in an area that is accessible to children or pets.

Common side effects:

Patients may have dizziness, headache, trouble sleeping, drowsiness, trouble concentrating, and/or unusual dreams during treatment with efavirenz, etaviren, and tenofovir disoproxil fumarate tablets. These side effects may be caused if you take etaviren, efavirenz, 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 depression. If you continue to have any of these side effects contact your healthcare provider right away if any of these side effects continue or if you bother you. It is possible that these symptoms may be more severe if efavirenz, efavirenz and tenofovir disoproxil fumarate tablets are used together with alcohol and/or medication that can cause depression, strange thoughts, or anxiety. Tell your healthcare provider right away if any of these side effects persist or if they bother you. It is possible that these symptoms may be more severe if efavirenz, efavirenz and tenofovir disoproxil fumarate tablets are used together with alcohol and/or medication that can cause depression, strange thoughts, or anxiety. 

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

• 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 other side effects while your child is taking efavirenz, etaviren, and tenofovir disoproxil fumarate tablets. 

Other side effects are rare in adults and children but may be more common in children. It is difficult to determine whether these side effects were due to etaviren, efavirenz and tenofovir disoproxil fumarate tablets because of the nature of the drug or from other medical conditions that could cause these side effects. It is important to report any side effect to your healthcare provider. If you have any concerns, your healthcare provider can discuss the risks and benefits of taking efavirenz, etaviren, 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 etaviren, efavirenz and tenofovir disoproxil fumarate tablets. 

• In some patients with advanced HIV infection (AIDS), skin 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. 

• Abnormal visual 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 etaviren, efavirenz and tenofovir disoproxil fumarate tablets. 

• Contact your healthcare provider before stopping etaviren, efavirenz 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 etaviren, efavirenz and tenofovir disoproxil fumarate tablets. Ask your healthcare provider or pharmacist for a more complete list of side effects of efaviren, efavirenz and tenofovir disoproxil fumarate tablets and all the medicines you will take. 

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

• Keep etaviren, efavirenz and tenofovir disoproxil fumarate tablets and all other medicines out of reach of children. 

• Store etaviren, efavirenz and tenofovir disoproxil fumarate tablets at room temperature 20° to 25°C (68° to 77°F) (see USP Controlled Room Temperature). 

• Keep etaviren, efavirenz 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 any medicines away make sure that children will not find them. 

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

• Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. Do not use etaviren, efavirenz and tenofovir disoproxil fumarate tablets for a condition for which it was not prescribed. Do not give etaviren, efavirenz, 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, efavirenz and tenofovir disoproxil fumarate tablets. If you would like more information, talk with your healthcare provider. You can ask questions about the ingredients of these tablets and their uses. 

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

Active Ingredients: efavirenz, etaviren, 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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