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What **TRUSTIVA** (**Efavirenz, Emtricitabine and Tenofovir DF**) is used for

TRUSTIVA can be used alone as a complete regimen, or in combination with other anti-HIV-1 medicines to treat people with HIV-1 infection.

How **TRUSTIVA (**Efavirenz, Emtricitabine and Tenofovir DF**) works**
TRUSTIVA helps block HIV-1 reverse transcriptase, a viral chemical in your body (enzyme) that is needed for HIV-1 to multiply, lowers the amount of HIV-1 in the blood (viral load) and may also help to increase the number of T cells (CD4⁺ cells), allowing your immune system to improve.

Before you use **TRUSTIVA** (**Efavirenz, Emtricitabine and Tenofovir DF**)

- When you must not use it
Pregnancy and lactation

Do not take **TRUSTIVA** (**Efavirenz, Emtricitabine and Tenofovir DF**) if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take **TRUSTIVA** (**Efavirenz, Emtricitabine and Tenofovir DF**) if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

If you are allergic to efavirenz, emtricitabine, tenofovir disoproxil fumarate or any of the other ingredients of this medicine.

- Before you start to use it

Tell your doctor if you have any heart disorder.

Tell your healthcare provider if you:

- 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.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some examples are listed below but not exhaustive:

- rifampicin
- clarithromycin;
- ganciclovir;
- lopinavir
- ritonavir
- midazolam
- or
- voriconazole

How to use **TRUSTIVA** (**Efavirenz, Emtricitabine and Tenofovir DF**)

- How much to use

The dose of **Trustiva** is one tablet once daily taken orally on an empty stomach.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking **TRUSTIVA** (**Efavirenz, Emtricitabine and Tenofovir DF**) for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking **TRUSTIVA** (**Efavirenz, Emtricitabine and Tenofovir DF**).

Tell your doctor immediately if you become pregnant while taking this medication.

- You should take **TRUSTIVA** on an empty stomach with water. They may make some side effects less bothersome if taken at bedtime.

- When your **TRUSTIVA** 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 TRUSTIVA and become harder to treat.

- ***Things you must not do***

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give **TRUSTIVA (Efavirenz, Emtricitabine and Tenofovir DF)** to anyone else, even if they have the same symptoms or condition as you.

- ***Things to be careful of***

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

TRUSTIVA (Efavirenz, Emtricitabine and Tenofovir DF) have the following effects:

• **Liver problems (hepatotoxicity):** with liver enlargement (hepatomegaly) and fat in the liver (steatosis).

• **“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 TRUSTIVA.

• **Serious psychiatric problems:** A small number of patients may experience severe depression, strange thoughts, or angry behavior while taking TRUSTIVA. Increases suicidal tendency in patients who have had mental illness.

• **Kidney problems** (including decline or failure of kidney function).

• **Other serious liver problems:** Some patients have experienced serious liver problems including liver failure resulting in transplantation or death in 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.** Some HIV patients treated with tenofovir DF developed thinning of the bones (osteopenia) which could lead to fractures. 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 TRUSTIVA. These side effects may be reduced if you take TRUSTIVA at bedtime on an empty stomach. They also tend to go away after you have taken the medicine for a few weeks. It is possible that these symptoms may be more severe if TRUSTIVA are used with alcohol or mood altering (street) drugs. Rash may be common.

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

Other possible side effects with TRUSTIVA:

• 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

• 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.

• 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.

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Some nervous system symptoms [e.g. confusion, slow thoughts and physical movement and delusions (false beliefs) or hallucinations (seeing or hearing things that others do not see or hear)] may occur months to years after

beginning TRUSTIVA therapy. Always notify your doctor or pharmacist if you have these symptoms or any side effects while taking TRUSTIVA.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI).

Storage and Disposal of TRUSTIVA (Efavirenz, Emtricitabine and Tenofovir DF)

- ***Storage***

Keep out of the reach and sight of children.

Store below 30 °C and protect from moisture.

- ***Disposal***

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.

Product Description

- ***What it looks like***

- Pink colored, capsule shaped, film coated tablets debossed with 'H' on one side and '128' on the other side.

- ***Ingredients***

- Active ingredient
Efavirenz,
Emtricitabine,
Tenofovir Disoproxil Fumarate

- Inactive ingredients

Microcrystalline Cellulose,
Croscarmellose sodium, Sodium
Lauryl sulfate, Hydroxypropyl
cellulose, Magnesium stearate and
Opadry II pink 85F9412

- ***MAL number:***

MAL16015040AZ

Manufacturer

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