

Estiva 600 (EFAVIRENZ TABLETS 600mg)

Efavirenz (600mg)

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What *ESTIVA-600* (Efavirenz) is used for

ESTIVA-600 (Efavirenz) contains an active ingredient efavirenz. Your doctor has prescribed Efavirenz for you because you have HIV infection. Efavirenz taken in combination with other antiretroviral medicines reduces the amount of the virus in the blood.

How *ESTIVA-600* (Efavirenz) works

Efavirenz works by lowering the amount of HIV-1 in the blood (viral load). Efavirenz must be taken with other anti- HIV medicines. When taken with other anti-HIV medicines, efavirenz has been shown to reduce viral load and increase the number of CD4+ cells, a type of immune cell in blood.

Before you use *ESTIVA-600* (Efavirenz)

- When you must not use it Pregnancy and lactation

Do not take *ESTIVA-600* (Efavirenz) if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take *ESTIVA-600* (Efavirenz) if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Tell your doctor if you

- have any heart disorder
- have problems with your liver or have hepatitis.
- have ever had mental illness or are using drugs or alcohol.
- have ever had seizures or are taking medicine for seizures [for example, phenytoin, carbamazepine or phenobarbital].

- 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.

Efavirenz may change the effect of other medicines, including ones for HIV, and cause serious side effects. Your doctor may change your other medicines or change their doses. Other medicines, including herbal products, may affect efavirenz.

Taking efavirenz with St. John's wort (*Hypericum perforatum*), a herbal product sold as a dietary supplement, or products containing St. John's wort is not recommended because it may decrease efavirenz levels and lead to increased viral load and possible resistance to efavirenz or cross- resistance to other anti-HIV drugs.

How to use *ESTIVA-600* (Efavirenz)

- How much to use

The dose for adults and children weighing greater than or equal to 40 kg is 600 mg once daily for the tablets.

The dose for children weighing 40 kg or less is calculated by body weight and is taken once daily as shown in the table below.

Pediatric Dose to be Administered Once Daily	
Body Weight (kg)	Efavirenz Dose (mg)
13 to <15	200
15 to <20	250
20 to <25	300
25 to <32.5	350
32.5 to <40	400
≥40	600

Your doctor or pharmacist will give you instructions for proper dosage.

ESTIVA-600 (Efavirenz) are available in strength of 600mg. They are not able to deliver all approved dose regimens of Efavirenz; other approved dosage forms and strengths of Efavirenz should be used in such cases.

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 *ESTIVA-600* (Efavirenz) 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.

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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 **ESTIVA-600 (Efavirenz)**.

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

You should take efavirenz on an empty stomach, preferably at bedtime.

- Swallow efavirenz with water.
- Taking efavirenz with food increases the amount of medicine in your body, which may increase the frequency of side effects.
- Taking efavirenz at bedtime may make some side effects less bothersome.
- Efavirenz must be taken in combination with other anti-HIV medicines. If you take only efavirenz, the medicine may stop

working.

- When your efavirenz supply starts to run low, get more from your doctor 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 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 **ESTIVA-600 (Efavirenz)** to anyone else, even if they have the same symptoms or condition as you.

Taking efavirenz with alcohol or other medicines causing similar side effects as efavirenz, such as drowsiness, may increase those side effects.

- 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.

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

Side effects

ESTIVA-600 (Efavirenz) have the following effects:

Common side effects: Many patients have dizziness, trouble sleeping, drowsiness, trouble concentrating, and/or unusual dreams during treatment with efavirenz. These side effects may be reduced if you take efavirenz 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 efavirenz is used with alcohol or mood altering (street) drugs.

Rash is common. Rashes usually go away without any change in treatment. In a small number of patients, rash may be serious.

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

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 **ESTIVA-600 (Efavirenz)** therapy. Always notify your doctor or pharmacist if you have these symptoms or any side effects while taking **ESTIVA-600 (Efavirenz)**.

Changes in body fat: Changes in body fat develop in some patients taking anti- HIV 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

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may also happen. The cause and long-term health effects of these fat changes are not known.

Liver problems: Some patients taking efavirenz 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.

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

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 ESTIVA-600 (Efavirenz)

- 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

Yellow, capsule shaped, film coated tablets debossed with 'H' on one side and '4' on the other side.

- Ingredients

- Active ingredient(s)

Efavirenz

- Inactive ingredients

Microcrystalline Cellulose, Croscarmellose sodium, Sodium lauryl sulfate, Hydroxy propyl cellulose, Lactose monohydrate, Magnesium stearate and Opadry yellow 03B52155.

- MAL number:

MAL18016019AZ

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