

EFAMAT TABLETS

Efavirenz (200mg, 600mg)

What is in this leaflet

1. What Efamat is used for
2. How Efamat works
3. Before you use Efamat
4. How to use Efamat
5. While you are using it
6. Side Effects
7. Storage and Disposal of Efamat
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What Efamat is used for

Efamat contains an active ingredient efavirenz which used to treat HIV infection.

Efamat taken in combination with other antiretroviral medicines reduces the amount of the virus in the blood.

How Efamat works

Efamat is a member of a class of antiretroviral medicines called non-nucleoside reverse transcriptase inhibitors (NNRTIs). It is an antiretroviral medicine that fights HIV infection by reducing the amount of virus in blood.

Before you take Efamat

- When you must not use it

Do not take Efamat if you are allergic to any of the ingredients in Efamat tablets.

Efamat should not be taken with some other medicines. (See Taking other medicines)

- Before you start use it

Inform your doctor about any past or present medical problems, including:

- liver disease (for example, chronic hepatitis B or C) or
- allergies,
- seizures,
- mental illness, or
- substance or alcohol abuse
- any medications, vitamins, or nutritional supplements including St. John's wort (*Hypericum perforatum*).

Inform your doctor if you are breast-feeding a baby, pregnant, or intend

to become pregnant. Tell your doctor if you are taking a medicine that contains efavirenz. Efamat should not be taken together with other medicines that contain efavirenz.

Women should notify their physician if they become pregnant while taking Efamat.

If you could get pregnant while receiving Efamat, a reliable form of barrier contraception should always be used with other methods of contraception including oral (pill) or other hormonal contraceptives (e.g., implants, injection). Efavirenz, 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 Efamat.

Inform your doctor immediately if you are pregnant or intend to become pregnant. If you are pregnant, you should take Efamat only if your doctor decide it is clearly needed.

Malformations have been seen in fetuses from animals treated with Efamat. Malformations have also been seen in newborns of women treated with Efamat during pregnancy; therefore, pregnancy should be avoided in women taking Efamat.

It is recommended that HIV-infected women should not breast-feed their infants because of the possibility that your baby can be infected with HIV through your breast milk. Talk with your doctor about the best way to feed your baby.

Use in children

Efamat has not been studied in children below 3 years of age or who weigh less than 13 kg. Efamat can be given to children 3 years of age and older who are able to swallow tablets.

Efamat must be taken with other medicines that act against the HIV

virus. If Efamat is started because your current treatment has not prevented the virus multiplying, another medicine you have not taken before must be started at the same time.

You must remain under the care of your doctor while taking Efamat. Tell your doctor immediately if you notice any symptoms of infection or inflammation.

Treatment with Efamat has not been shown to reduce the risk of passing on HIV infection to others through sexual contact or blood contamination.

This product has been prescribed only for you. You should not give it to others.

- Taking other medicines

Medicines that should not be administered concurrently when taken with Efamat include astemizole, cisapride, terfenadine, midazolam, triazolam, pimozide, bepridil, and ergot derivatives. Do not take Efamat with St. John's wort (*Hypericum perforatum*), an herbal product sold as a dietary supplement, or products containing St. John's wort.

How to use Efamat

- 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.

Body Weight (kg)	Efamat Tablets 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

EFAMAT TABLETS

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

- When to use it

Efamat tablets may be taken with or without food. Efamat must be taken every day. Efamat should never be used alone to treat HIV. Efamat must always be taken in combination with other anti-HIV medications.

- How long to use it

It is important that you take Efamat exactly as your doctor prescribes. You should not stop taking it without first consulting your doctor.

- If you forget to use it

Try not to miss a dose. If you do miss a dose, take the next dose as soon as possible, but do not double the next dose. If you need help in planning the best times to take your medicine, ask your doctor or pharmacist.

When your Efamat supply starts to run low, get more from your doctor or pharmacist. 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 use too much (overdose)

If you take too much Efamat consult your doctor or clinic.

While you are using it

- Things you must do

Take the medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Efamat.

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

- Things you must not do

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

Do not take any new medicines without consulting your doctor. Do not give Efamat to anyone else, even if they have the same symptoms or conditions as you.

- Things to be careful of

Dizziness, impaired concentration, and drowsiness have been reported during treatment with Efamat. If you experience these symptoms you should avoid potentially hazardous tasks such as driving or operating machinery.

Side effects

Any medicine may have unintended or undesirable effects, so-called side effects. Efamat has been shown to be generally well tolerated. The most frequently reported adverse reactions associated with Efamat in combination with other anti-HIV medications include rash, nausea, dizziness, headache, and fatigue.

The most notable unwanted effects are skin rash and nervous system symptoms that include dizziness, insomnia, somnolence (drowsiness), impaired concentration, and abnormal dreaming.

You should consult your doctor if you have a rash, since some rashes may be serious; however, most cases of rash disappear without any change to your treatment with Efamat. Rash was more common in children than in adults treated with Efamat.

The nervous system symptoms tend to occur when treatment is first started, but generally decrease in the first few weeks. If you are affected your doctor may suggest that you take Efamat at bedtime and on an empty stomach. Rarely, some patients have more serious symptoms that may affect mood or

the ability to think clearly. These include depression, suicidal thoughts, angry behavior, and strange thoughts. Some patients have actually committed suicide.

These problems tend to occur more often in those who have a history of mental illness. Always notify your doctor if you have these symptoms or any side effects while taking Efamat.

Rarely, disturbances of coordination and balance, seizures, itching, stomach ache, blurred vision, breast enlargement in men, liver failure, inflammation of the pancreas, increased fat appearing in areas such as the neck, breasts, abdomen, and back, flushing, tremors, and ringing in the ears have been reported in patients receiving Efamat.

Other side effects may occur with Efamat. Your doctor or pharmacist has a more complete list of side effects. Inform your doctor promptly about these or any other undesirable effects, especially if not mentioned in this leaflet. If the condition persists or worsens, seek medical attention.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public→Reporting Medicinal Problems/Side Effects/ AEFI/ Vaccine Safety).

Storage and Disposal of Efamat

- Storage

Keep Efamat tablet out of the sight and reach of children.

Don't store Efamat tablet above 30 °C.

Store it in its original container. Don't take Efamat tablet after the expiry date shown on the carton.

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Efavirenz (200mg, 600mg)

- 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

Efamat tablets 200mg: Peach colored, oval, film coated tablets, debossed with "3X" on one side and "M" on other side.

Efamat tablets 600mg: Peach colored capsule shaped, film coated tablets, debossed with "M109" on one side and plain on other side.

- Ingredients

- Active ingredient (s)
Efavirenz

- Inactive ingredients
Cellulose Microcrystalline,
Croscarmellose sodium,
Hydroxypropyl cellulose,
Sodium lauryl Sulfate, Lactose monohydrate, Magnesium Stearate, film coat
{Hypromellose, Titanium dioxide, PEG 400, Iron oxide yellow, Iron oxide red}.

- MAL number:

Efamat 600mg : MAL11030099AZ
Efamat 200mg : MAL16115033AZ

Manufacturer

Mylan Laboratories Limited
F-4 & F-12, MIDC, Malegaon,
Sinnar, Nashik - 422 113,
Maharashtra, INDIA

Product Registration Holder

Pahang Pharmacy Sdn. Bhd.
Lot 5979, Jalan Teratai,
5 ½ Miles off Jalan Meru,
Klang, Selangor, MALAYSIA.

Date of Revision

09/06/2017

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