

**PATIENT INFORMATION LEAFLET**

## PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

### Efavirenz tablets 600 mg

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

**In this leaflet:**

1. What Efavirenz tablets 600 mg is and what it is used for
2. Before you take Efavirenz tablets 600 mg
3. How to take Efavirenz tablets 600 mg
4. Possible side effects
5. How to store Efavirenz tablets 600 mg
6. Further information

#### **1. WHAT EFAVIRENZ TABLETS 600 MG IS AND WHAT IT IS USED FOR**

Efavirenz tablets 600 mg belongs to a class of antiretroviral medicines called non-nucleoside reverse transcriptase inhibitors (NNRTIs). It is **an antiretroviral medicine that fights human immunodeficiency virus (HIV) infection** by reducing the amount of the virus in the blood.

Efavirenz tablets 600 mg is used in antiretroviral combination therapy for the treatment of HIV infection. Efavirenz tablets 600 mg reduces the amount of HIV virus in your body and keeps it at a low level. It also increases CD4 cell counts. CD4 cells are a type of white blood cell that plays an important role in maintaining a healthy immune system to help fight infection. Response to treatment with Efavirenz tablets 600 mg varies between patients. Your doctor or health care provider will be monitoring the effectiveness of your treatment.

Efavirenz tablets 600 mg may improve your condition, but it is not a cure for your HIV infection. HIV infection is a disease spread by contact with blood or sexual contact with an infected individual. Treatment with Efavirenz tablets 600 mg has not been shown to eliminate the risk of passing HIV infection on to others by sexual contact or by blood transfer. Therefore, you must continue to take appropriate precautions to avoid giving the virus to others.

During your treatment, other infections linked to your weakened immunity (opportunistic infections) may arise. These will require specific and sometimes preventive treatment.

#### **2. BEFORE YOU TAKE EFAVIRENZ TABLETS 600 MG**

**Do not take Efavirenz tablets 600 mg if:**

- you are allergic (hypersensitive) to efavirenz or any of the other ingredients of Efavirenz tablets 600 mg (see section 6, What Efavirenz tablets 600 mg contains);
- if you are currently taking St. John's wort (*Hypericum perforatum*) (a herbal remedy used for depression and anxiety)

**Take special care with Efavirenz tablets 600 mg**

Before using this medicine, you should have told your doctor or health care provider:

- if you suffer from liver disease (such as hepatitis);

- about past or present medical problems including allergies, seizures, mental illness, or substance or alcohol abuse.

A mild-to-moderate skin rash commonly develops in the first two weeks after starting with Efavirenz tablets 600 mg, this usually resolves within 4 weeks of the beginning of treatment; in case of a progression to a severe rash you need to tell your doctor or health care provider immediately and Efavirenz tablets 600 mg may have to be discontinued.

Following the start of Efavirenz tablets 600 mg central nervous system side effects are very common, usually starting in the first week of treatment. These may include dizziness, confusion, insomnia, somnolence, impaired concentration and abnormal dreaming. Other side effects are amnesia, hallucinations, euphoria, depression, suicidal ideation or psychosis (see section 4). These usually resolve within four weeks of the start of treatment.

In some patients with advanced HIV infection (AIDS) and a history of opportunistic infection, 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 or health care provider immediately.

You will need to take Efavirenz tablets 600 mg every day. This medicine helps to control your condition, but it is not a cure for HIV infection. You may continue to develop other infections and other illnesses associated with HIV disease. You should keep in regular contact with your doctor or health care provider. Do not stop taking your medicine without first talking to your doctor or health care provider.

### **Taking other medicines**

Please tell your doctor, health care provider or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. These may affect the action of Efavirenz tablets 600 mg, or Efavirenz tablets 600 mg may affect their action.

- Efavirenz tablets 600 mg must not be taken with herbal preparations containing St John's wort (*Hypericum perforatum*)
- Efavirenz tablets 600 mg should not be taken with the following agents: astemizole, cisapride, terfenadine, midazolam, triazolam, pimozone, bepridil and ergot alkaloids (for example, ergotamine, dihydroergotamine, ergonovine, and methylergonovine). Taking these medicines with Efavirenz tablets 600 mg may cause serious and / or life-threatening side effects.
- Efavirenz tablets 600 mg should not be used as part of a triple combination regimen consisting of efavirenz, didanosine and tenofovir because of inferior efficacy compared to other combination regimens;
- Efavirenz tablets 600 mg may also interact with the following medicines and may make any side effects worse or may impact on the either agent's efficacy:
  - amprenavir, atazanavir, darunavir, indinavir, lopinavir, maraviroc, nelfinavir, ritonavir, saquinavir and tipranavir (antiviral agents).
  - methadone, buprenorphine (used to treat severe pain or opioid dependency);
  - clarithromycin, rifabutin or rifampicin (antibacterials/antituberculotics),
  - atorvastatin, pravastatin, or simvastatin (lipid-lowering medicines, also called statins)
  - hormonal contraceptives such as birth control pills, an injected contraceptive or a contraceptive implant. Therefore, you should employ an alternative contraceptive method such as barrier contraception (e.g. condoms), if you are taking Efavirenz tablets 600 mg (see also "pregnancy and breast-feeding")..
  - voriconazole, itraconazole, posaconazole (antifungals)
  - amodiaquine /artesunate, quinine, lumefantrine, halofantrine, artemisine (antimalarials)
  - carbamazepine, phenytoin (anticonvulsants)

- diltiazem, verapamil, felodipine, nifedipine, nicardipine (calcium channel blocker)
- tacrolimus, cyclosporine, sirolimus (immunosuppressants)
- warfarin (medicine for prophylaxis of blood clots)

### **Taking Efavirenz tablets 600 mg with food and drink**

Efavirenz tablets 600 mg should be taken on an empty stomach or with a low-fat meal.

### **Pregnancy**

Inform your doctor immediately if you are pregnant or intend to become pregnant. If you are pregnant, you should take Efavirenz tablets 600 mg only if you and your doctor decide it is clearly needed.

Malformations have been seen in foetuses from animals and in newborns of women treated with efavirenz during pregnancy; therefore, pregnancy should be avoided in women receiving Efavirenz tablets 600 mg.

If you are a woman receiving Efavirenz tablets 600 mg a reliable form of barrier contraception (for example a condom) should always be used, with other methods of contraception including oral (pill) or other hormonal contraceptives (for example implant, injection).

### **Breastfeeding**

If a mother wants to breastfeed her baby, her doctor or healthcare provider should be asked for advice on the risks and benefits. Treatment of mother and/or child with medicines may be needed.

Generally it is recommended that HIV-infected women should not breast-feed their infants because of the possibility that the baby may be infected with HIV through the breast milk.

### **Driving and using machines**

Dizziness, impaired concentration, and drowsiness have been reported during treatment with Efavirenz tablets 600 mg. If you experience these symptoms you should avoid potentially hazardous tasks such as driving or operating machinery.

### **Important information about some of the ingredients of Efavirenz tablets 600 mg**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. HOW TO TAKE EFAVIRENZ TABLETS 600 MG**

Always take Efavirenz tablets 600 mg exactly as your doctor or health care provider has told you. You should check with your doctor, health care provider or pharmacist if you are not sure.

The usual daily dose for adults and adolescents weighing 40 kg or more is 600 mg, given once daily.

### **Children**

Since Efavirenz tablets 600 mg can not be divided, Efavirenz tablets 600 mg is not suitable for patients whose body weight is less than 40 kg. In these cases another formulation should be used, e.g. a tablet/capsule containing less efavirenz, or an oral solution.

Efavirenz is not recommended for use in children weighing less than 13 kg due to a lack of data on safety and efficacy.

Efavirenz tablets 600 mg should be taken on an empty stomach, e.g. in the evening before going to bed.

Efavirenz tablets 600 mg will always be taken in combination with other antiretroviral medication; please make sure to follow also the instructions within the supplied package leaflet of the other products.

**If you take more Efavirenz tablets 600 mg than you should**

If you take too much Efavirenz tablets 600 mg consult your doctor or local first aid hospital.

**If you forget to take Efavirenz tablets 600 mg**

Try not to miss a dose. If you do miss a dose, take the next dose as soon as possible. However, when the next regular dose is due within 12 hours, then simply take your normal next dose at its due time. Do not double the dose.

**If you stop taking Efavirenz tablets 600 mg**

Do not stop taking Efavirenz tablets 600 mg unless you experience serious side effects or your doctor has told you to. 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 have any further questions on the use of this product, ask your doctor or pharmacist.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Efavirenz tablets 600 mg can cause side effects, although not everybody gets them.

The most frequently reported adverse reactions associated with Efavirenz tablets 600 mg in combination with other anti-HIV medicines include skin rash, dizziness, nausea, 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 Efavirenz tablets 600 mg. Rash was more common in children than in adults treated with Efavirenz tablets 600 mg.

*Very commonly* reported (greater than 1 in every 10 patients treated) side effects are rash, and changes in fat metabolism as shown by increase in lipid levels in the blood.

*Commonly* reported (greater than 1 in every 100 patients treated) side effects are dizziness, insomnia, somnolence, impaired concentration, abnormal dreaming, headache, fatigue, anxiety, depression, disturbed liver function as detected by elevation of liver enzymes in blood, pruritus, abdominal pain, diarrhoea, nausea, vomiting.

The following side effects are *uncommon* (between 1 in 1,000 and 1 in 100 patients treated): psychosis (mental state with severely impaired thought and perception). The likelihood is increased in those with a history of psychiatric disease. Affect lability, aggression, abnormal thoughts, nervousness, forgetfulness, problems with coordination, vertigo, confusion, fits (seizures), suicidal thoughts, acute hepatitis, acute pancreatitis, blurred vision, breast enlargements in males (gynaecomastia), and allergic reaction (hypersensitivity) that may cause severe skin reactions (erythema multiforme).

*Side effects reported with an unknown frequency:* coordination and balance disturbances, flushing; ringing or other persistent noise in the ears (tinnitus), and tremor (shaking).

Combination antiretroviral therapy may cause hyperlipidaemia (increased fats in the blood), resistance to insulin, raised sugar and lactic acid in the blood.

Moreover, it may cause a condition called lactic acidosis, which is a build up of lactic acid in the body that can cause dehydration and coma which have been reported on rare occasions in patients taking

certain antiretrovirals (so-called NRTIs). Deep, rapid breathing, drowsiness, and non specific symptoms such as nausea, vomiting and stomach pain, may indicate the development of lactic acidosis.

Combination antiretroviral therapy may cause changes in body shape due to changes in fat distribution. These may include loss of fat from legs, arms and face, increased fat in the abdomen (belly) and other internal organs, breast enlargement and fatty lumps on the back of the neck ('buffalo hump'). The cause and long-term health effects of these conditions are not known at this time.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

## **5. HOW TO STORE EFAVIRENZ TABLETS 600 MG**

Keep out of the reach of children.

Do not store above 30 °C. Store in the original container.

Do not use Efavirenz tablets 600 mg after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Do not use Efavirenz tablets 600 mg if you notice any distortion in the shape of the tablet

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

## **6. FURTHER INFORMATION**

### **What Efavirenz tablets 600 mg contains**

The active ingredient is 600 mg efavirenz.

Tablet core: croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose and sodium lauryl sulfate.

Film-coating: hypromellose, iron oxide black, iron oxide red, iron oxide yellow, polyethylene glycol 400 and titanium dioxide.

### **What Efavirenz tablets 600 mg looks like and contents of the pack**

Off-white coloured, capsule shaped, film-coated tablets, plain on both sides.

The tablets should not be divided.

50ml white opaque HDPE container with white LDPE tear-off cap with white expanded polyethylene foam filler.

Pack size: 30 tablets.

### **Supplier**

Strides Shasun Limited  
Strides House  
Bilekahalli, Bannerghatta Road  
560076 Bangalore  
Karnataka  
India  
Phone : 91-80-66580289/290  
Fax: 91-80-66580200

**and**

### **Manufacturer**

Strides Shasun Limited  
36/7, Suragajakkanahalli Indlavadi Cross  
Anekal Taluk  
562 106 Bangalore  
Karnataka  
India  
Telephone: 91-80- 66580600  
Fax: 91-80-66580606

Email: [aloka.sengupta@stridesarco.com](mailto:aloka.sengupta@stridesarco.com)

Email: [info@stridesarco.com](mailto:info@stridesarco.com)

For any information about this medicinal product, please contact the local representative of the supplier:

Region: **French Africa**

**Address: APHAD**

416 Rue Dubios De Salingly

Akwa, Doula

**Cameroon.**

**Tel Office (Board line) +237 3 43 0435**

Contact person: Vipin Vikraman Pillai

Email: [vipin.v@stridesarco.com](mailto:vipin.v@stridesarco.com)

Region: **Africa**

Address: **Strides Vital Nigeria Limited,**

Plot No. 02, Ladipo Oluwole Avenue,

Opposite Cocoa Warehouse,

Off Oba Akran Road,

Ikeja Industrial Estate,

Ikeja, Lagos State,

**Nigeria.**

Tel: + 234-1-4969002

Fax: + 234-1-4969006

Contact person: Mr.Mathew Philip

Email: [mathew\\_ph@yahoo.co.uk](mailto:mathew_ph@yahoo.co.uk)

Region: **South Africa**

Address: **Strides South Africa**

Ground Floor, 6 De Veer Lane

Arcadia

Pretoria

**South Africa 0007**

**Tel: 0027 012 321 9089**

Contact person: Eduan Stoltz

Email: [ifdas@intekom.co.za](mailto:ifdas@intekom.co.za)

Region: **Asia**

**Name: Ms. Phoung**

**Strides Arcolab Ltd**

377/80 Le Dai Hanh Street,

Ward 11, District 11

Ho Chi Minh City,

**Vietnam.**

Tel: 008488580211

Email: [stridesarco@hcm.vnn.vn](mailto:stridesarco@hcm.vnn.vn)