Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Before you start
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- Read all of this leaflet carefully before you take Efavirenz 600 mg.

What is this inefal
1. What Efavirenz 600 mg is and what it is used for
Efavirenz 600 mg Film-coated tablets, contains the active substance efavirenz, belongs to a class of antiretroviral medicines called non-nucleoside reverse transcriptase inhibitors (NNRTIs). Efavirenz is an antiretroviral medicine that fights human immunodeficiency virus (HIV-1) infection by reducing the amount of the virus in blood. It is used by adults, adolescents and children 3 years of age and older.

2. What you need to know before you take Efavirenz 600 mg
Do not take Efavirenz 600 mg:
- if you are allergic to efavirenz or any of the other ingredients of this medicine (see section 4).
- if you have had severe liver disease.
- if you are currently taking any of the following medicines:
  - anticoagulants or antiplatelet agents (to prevent or to treat symptoms of heart attacks or strokes) - biperidin (used to treat heart disease) - gold complexes (used to treat heart conditions) - ergot alkaloids (for example, ergotamine, dihydroergotamine, ergonovine, and methylergometrine) (used to treat menstrual and cluster headaches) - antipsychotic medicines - pimozide (used to treat certain mental conditions) - St John's wort (ephedrae perforata) (a herbal remedy used for depression and anxiety).

If you are taking any of these medicines, tell your doctor immediately. Taking these medicines with Efavirenz 600 mg could create the potential for serious and/or life-threatening side-effects or stop Efavirenz 600 mg from working properly. Warning and precautions
Talk to your doctor before taking Efavirenz 600 mg.

- Efavirenz 600 mg must be taken with other medicines that act against the HIV virus. If Efavirenz 600 mg is started because your current treatment has not prevented the virus from multiplying, another medicine you have not taken before must be started at the same time.

- You can still pass on HIV when you take this medicine, although the risk is lowered by using effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people. This medicine is not a cure for HIV infection and you may continue to develop infections or other illnesses associated with HIV disease.

- You must remain under the care of your doctor while taking Efavirenz 600 mg.

Tell your doctor:
- if you have a history of mental illness, depression, or substance or alcohol abuse. Tell your doctor immediately if you feel depressed, have suicidal thoughts or attempt suicide.
- if you have a history of convulsions (fits or seizures) or if you are being treated with anticonvulsant therapy such as carbamazepine, phenobarbital and phenytoin. These medicines may need to be checked at the level of anticonvulsant medicine in your blood to ensure that it is not affected while taking Efavirenz 600 mg. Your doctor may give you a different anticonvulsant
- if you have a history of liver disease, including active chronic hepatitis. Patients with chronic hepatitis B or C or treated with combination antiretroviral agents have a higher risk for severe and potentially life-threatening liver problems. Your doctor may conduct blood tests in order to check how well your liver is working or may switch you to another medicine. If you have any severe liver disease, do not take Efavirenz 600 mg (see section 2). Do not take Efavirenz 600 mg if you:

- changes in body weight, redistribution, accumulation or loss of body fat may occur in patients receiving combination antiretroviral therapy. Tell your doctor if you notice any of these side effects.
- bone problems. Some patients taking combination antiretroviral therapy may develop bone problems, such as called osteoporosis (loss of bone tissue caused by loss of bone supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index and previous smoking are among other factors that may increase the risk for these bone problems. Signs of osteoporosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms please inform your doctor.

Children and adolescents
Efavirenz is not recommended for children under the age of 3 years or weighing less than 13 kg because it has not been adequately studied in these patients.

Other medicines and Efavirenz 600 mg
You must not take Efavirenz 600 mg with certain medicines. These are listed under Do not take Efavirenz 600 mg, at the start of Section 4. They include some common medicines and a herbal remedy (St John’s wort) which can cause serious interactions.

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take, any of the other medicines listed under Do not take Efavirenz 600 mg. Efavirenz 600 mg may interact with other medicines, including herbal preparations such as St John’s wort. A new medicine started because your current treatment has not prevented the virus from multiplying, another medicine you have not taken before must be started at the same time.

- medicines used to treat the hepatitis C virus: boceprevir, telaprevir
- medicines used to treat bacterial infections, including tuberculosis and AIDS-related mycobacterium avium complex: chloramphenicol, rifabutin, rifampicin. Your doctor may consider changing your dose or giving you an alternative antifungal
- medicines used to treat fungal infections (antifungals): voriconazole. Efavirenz 600 mg may reduce the amount of voriconazole in your blood and voriconazole may increase the amount of Efavirenz 600 mg in your blood. If you take these two medicines together, the dose of voriconazole must be monitored and possibly reduced. You may check with your doctor first to make sure that voriconazole is being used safely.
- medicines used to lower blood fats (also called statins): atorvastatin, pravastatin. Efavirenz 600 mg may reduce the amount of atorvastatin in your blood.
- medicines used to treat malaria: artemether/lumefantrine. Efavirenz may reduce the amount of artemether/lumefantrine in your blood.
- medicines used to treat tuberculosis: isoniazid. Efavirenz may reduce the amount of isoniazid in your blood.
- medicines used to treat tuberculosis: pyrazinamide. Efavirenz may reduce the amount of pyrazinamide in your blood.

Possible side effects
- efavirenz side effects (medicines used to treat tuberculosis): pyridoxine (vitamin B6), isoniazid (INH), and rifabutin. Your doctor may consider changing your dose or giving you an alternative antifungal.

- medicines used to treat urinary incontinence: neostigmine, pyridostigmine. Efavirenz may reduce the amount of neostigmine and pyridostigmine in your blood.
- medicines used to treat fungal infections (antifungals): itraconazole. Efavirenz may reduce the amount of itraconazole in your blood.
- medicines used to treat HIV infection: didanosine, zidovudine. Efavirenz may reduce the amount of didanosine and zidovudine in your blood.
- medicines used to treat fungal infections (antifungals): voriconazole. Efavirenz may reduce the amount of voriconazole in your blood and voriconazole may increase the amount of Efavirenz 600 mg in your blood. If you take these two medicines together, the dose of voriconazole must be monitored and possibly reduced. Your doctor may need to change your dose of methadone.

There are no other side effects not listed in this leaflet.

What to do now
- keep this leaflet. You may need to read it again.
- keep this leaflet in case you need to refer to it later.

- review all of this leaflet carefully before you start taking this medicine.
Efavirenz 600 mg with food and drink
Taking Efavirenz 600 mg on an empty stomach may reduce the undesirable effects. Grapefruit juice should be avoided when taking Efavirenz 600 mg.

Pregnancy and breast-feeding
Women should not get pregnant during treatment with Efavirenz 600 mg and for 2 months afterwards. Your doctor may require you to take a pregnancy test to ensure you are not pregnant before starting treatment with Efavirenz 600 mg. If you could get pregnant while receiving Efavirenz 600 mg, you need to use a reliable method of contraception (for example, a condom) with other methods of contraception including oral pill or other hormonal contraceptives (for example, implants, injection). Efavirenz may remain in your blood for a time after therapy is stopped. Therefore, you should continue to use contraceptive measures, as above, for 12 weeks after you stop taking Efavirenz 600 mg.

Tell your doctor immediately if you are pregnant or intend to become pregnant. If you are pregnant or intend to become pregnant, do not use Efavirenz 600 mg. If you are unsure if you are pregnant, you should take a pregnancy test to decide it is clearly needed. Ask your doctor or pharmacist for advice before taking any medicine.

The most common unwanted effects are caused byEfavirenz. They are:

- tiredness
- itching
- drowsiness, problems with coordination or balance
- abnormal dreams, difficulty concentrating, dizziness
- skin rash
- rash was more common in users in 10

The most common unwanted effects are:

- nervousness, forgetfulness, confusion, fitting (seizures), abnormal thoughts
- blurred vision
- a feeling of spinning or tilting (vertigo)
- pain in the abdomen (stomach) caused by inflammation of the pancreas
- allergic reaction (hypersensitivity) that may cause severe skin reactions (erythema multiforme, Stevens-Johnson syndrome)
- yellow skin or eyes, itching, or pain in the abdomen (stomach) caused by swelling
- breast enlargement in males
- angry behaviour, mood being affected, seeing or hearing things that are not really there (hallucinations), manic (mental condition characterised by episodes of overactivity, elation or irritability), paranoia, suicidal thoughts
- wheezing, cough or other persistent noise in the ears
- tremor (shaking)
- flushing
- taste changes
- increased cholesterol in the blood

Rare (effects that affect less than 1 in 10,000)

- itchy rash caused by a reaction to sunlight
- liver failure, in some cases leading to death or liver transplant, has occurred with efavirenz. Most cases occurred in patients who already had liver disease, but there have been a few reports in patients without any existing liver disease
- unexplained feelings of distress not associated with hallucinations, but it may be difficult to think clearly or sensibly
- suicide

Combined antiretroviral therapy may change your body shape, by changing the way body fat and muscle are distributed. This may affect the way some medicines work. You may lose weight from your face and gain fat around the abdomen (tummy) and other internal organs, get larger breasts or fatty lumps on the back of the neck (buffalo hump). The cause and long-term health effects of these changes are not yet well known.

Combination antiretroviral therapy may also cause raised lactic acid and sugar in the blood, increased fat levels in the blood (hyperlipidaemia) and resistance to insulin. Your doctor will test for these changes.

Rating of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

4. How to store Efavirenz 600 mg

Always keep this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will give you instructions for proper dosing.

The dose for adults is 600 mg once daily.

The dose for Efavirenz 600 mg to be increased or decreased if you are also taking other medicines (See Other medicines and Efavirenz 600 mg).

If you take too much Efavirenz 600 mg then you should:

- take a overdose as soon as possible, but do not take a double dose to make up for a forgotten dose. If you need help in deciding the best times to take the medicine, ask your doctor or pharmacist.

When your Efavirenz 600 mg supply starts to run low, get more from your doctor or pharmacist as soon as possible so that you do not run out of medicine.

The most notable unwanted effects reported with Efavirenz in combination with other HIV medicines are skin rash and nervous system symptoms.

You should consult your doctor if you have a rash, even if it is small. There is no particular advice for treatment. Keep the medicine container with you so that you can easily describe what you have taken.

If you forget to take Efavirenz 600 mg

The dose for Efavirenz 600 mg may need to be increased or decreased if you are also taking other medicines (See Other medicines and Efavirenz 600 mg).

If you take more Efavirenz 600 mg than you should

If you take too much Efavirenz 600 mg, contact your doctor or nearest emergency centre immediately.

Stop taking this medicine. Keep the container with you so that you can easily describe what you have taken.

If you stop taking Efavirenz 600 mg

You can also report side effects directly via the Yellow Card Scheme, website www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

- Get a second opinion. This may affect the way some medicines work. You may lose weight from your face and gain fat around the abdomen (tummy) and other internal organs, get larger breasts or fatty lumps on the back of the neck (buffalo hump). The cause and long-term health effects of these changes are not yet well known.

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the bottle or blister.

You can also report side effects directly via the Yellow Card Scheme, website www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Efavirenz 600 mg

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the bottle or blister and on the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Efavirenz 600 mg tablets contain

Each Efavirenz 600 mg film-coated tablet contains 600 mg of the active substance efavirenz.

The other ingredients of the tablet core are: magnesium stearate, lactose monohydrate, sodium laurilsulfate, croscarmellose sodium, hydroxypropylcellulose, microcrystalline cellulose.

The expiry date refers to the last day of that month.

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This medicinal product is authorised in the Member States of the EEA under the following names:

The Netherlands: Efavirenz Hetero 600 mg filmomhulde tabletten

Tests may show:

- increased liver enzymes in the blood
- increased triglycerides (fatty acids) in the blood

Uncommon (occurs in 1 to 10 users in 1,000)

- hypoglycaemia
- abnormal blood test results
- mood disorders (such as depression)
- dizziness
- cough
- skin rash
- nervousness, forgetfulness, confusion, fitting (seizures), abnormal thoughts
- blurred vision
- a feeling of spinning or tilting (vertigo)
- pain in the abdomen (stomach) caused by inflammation of the pancreas
- allergic reaction (hypersensitivity) that may cause serious skin reactions (erythema multiforme, Stevens-Johnson syndrome)
- yellow skin or eyes, itching, or pain in the abdomen (stomach) caused by swelling
- breast enlargement in males
- angry behaviour, mood being affected, seeing or hearing things that are not really there (hallucinations), manic (mental condition characterised by episodes of overactivity, elation or irritability), paranoia, suicidal thoughts
- wheezing, cough or other persistent noise in the ears
- tremor (shaking)
- flushing
- taste changes
- increased cholesterol in the blood

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