

Package leaflet: Information for the user
Efavirenz Medical Valley 600 mg film-coated tablets
efavirenz

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

- Keep this leaflet. You may need to read it again.
- 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.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Invented name] is and what it is used for
2. What you need to know before you take [Invented name]
3. How to take [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

1. What [Invented name] is and what it is used for

[Invented name], which contains the active substance efavirenz, 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-1)** infection by reducing the amount of the virus in blood. It is used by adults, adolescents and children 3 months of age and older and weighing at least 3.5 kg.

Your doctor has prescribed [Invented name] for you because you have HIV infection.

[Invented name] taken in combination with other antiretroviral medicines reduces the amount of the virus in the blood. This will strengthen your immune system and reduce the risk of developing illnesses linked to HIV infection.

2. What you need to know before you take [Invented name]

Do not take [Invented name]:

- **if you are allergic** to efavirenz or any of the other ingredients of this medicine (listed in section 6). Contact your doctor or pharmacist for advice.
- **if you have severe liver disease.**
- **if you have a heart condition, such as changes in the rhythm or rate of the heart beat, a slow heart beat, or severe heart disease.**
- if any member of your family (parents, grandparents, brothers or sisters) has died suddenly due to a heart problem or was born with heart problems.
- if your doctor has told you that you have high or low levels of electrolytes such as potassium or magnesium in your blood.
- **if you are currently taking** any of the following medicines (see also “Other medicines and [Invented name]”):
 - **astemizole or terfenadine** (used to treat allergy symptoms)
 - **bepiridil** (used to treat heart disease)
 - **cisapride** (used to treat heartburn)
 - **ergot alkaloids** (for example, ergotamine, dihydroergotamine, ergonovine, and methylergonovine) (used to treat migraine and cluster headaches)
 - **midazolam or triazolam** (used to help you sleep)

- **pimozide, imipramine, amitriptyline or clomipramine** (used to treat certain mental conditions)
- **elbasvir or grazoprevir** (used to treat hepatitis C)
- **St. John's wort** (*Hypericum perforatum*) (a herbal remedy used for depression and anxiety)
- **flecainide, metoprolol** (used to treat irregular heart beat)
- **certain antibiotics** (macrolides, fluoroquinolones, imidazole)
- **triazole antifungal agents**
- **certain antimalarial treatments**
- **methadone** (used to treat opiate addiction)

If you are taking any of these medicines, tell your doctor immediately. Taking these medicines with [Invented name] could create the potential for serious and/or life-threatening side-effects or stop [Invented name] from working properly.

Warnings and precautions

Talk to your doctor before taking [Invented name]

- **[Invented name] must be taken with other medicines that act against the HIV virus.** If [Invented name] 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.
- 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 [Invented name].
- **Tell your doctor:**
 - **if you have a history of mental illness**, including depression, or of substance or alcohol abuse. Tell your doctor immediately if you feel depressed, have suicidal thoughts or have strange thoughts (see section 4, *Possible side effects*).
 - **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. If you are taking any of these medicines, your doctor may need to check the level of anticonvulsant medicine in your blood to ensure that it is not affected while taking [Invented name]. 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 and 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 severe liver disease, do not take [Invented name]** (see section 2, *Do not take [Invented name]*).
 - **if you have a heart disorder, such as abnormal electrical signal called prolongation of the QT interval.**
- **Once you start taking [Invented name], look out for:**
 - **signs of dizziness, difficulty sleeping, drowsiness, difficulty concentrating or abnormal dreaming.** These side effects may start in the first 1 or 2 days of treatment and usually go away after the first 2 to 4 weeks.
 - **signs of confusion, slow thoughts and physical movement, and delusions (false beliefs) or hallucinations (seeing or hearing things that others do not see or hear).** These side effects may occur months to years after beginning <Invented name> therapy. If you notice any symptoms, please inform your doctor.

- **any signs of skin rash.** If you see any signs of a severe rash with blistering or fever, stop taking [invented name] and tell your doctor at once. If you had a rash while taking another NNRTI, you may be at a higher risk of getting a rash with [Invented name].
- **any signs of inflammation or infection.** 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 tell your doctor immediately.

In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.

- **bone problems.** Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index, among others, may be some of the many risk factors for developing this disease. Signs of osteonecrosis 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 months or weighing less than 3.5 kg because it has not been adequately studied in these patients

Other medicines and [Invented name]

You must not take [Invented name] with certain medicines. These are listed under Do not take [Invented name], at the start of Section 2. 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 other medicines.

[Invented name] may interact with other medicines, including herbal preparations such as *Ginkgo biloba* extracts. As a result, the amounts of [Invented name] or other medicines in your blood may be affected. This may stop the medicines from working properly, or may make any side effects worse. In some cases, your doctor may need to adjust your dose or check your blood levels. **It is important to tell your doctor or pharmacist if you are taking any of the following:**

- **Other medicines used for HIV infection:**
 - protease inhibitors: darunavir, indinavir, lopinavir/ritonavir, ritonavir, ritonavir boosted atazanavir, saquinavir or fosamprenavir/saquinavir. Your doctor may consider giving you an alternative medicine or changing the dose of the protease inhibitors.
 - maraviroc
 - the combination tablet containing efavirenz, emtricitabine and tenofovir should not be taken with [Invented name] unless recommended by your doctor since it contains efavirenz, the active ingredient of [Invented name].

- **Medicines used to treat infection with the hepatitis C virus:** boceprevir, telaprevir, elbasvir/grazoprevir, simeprevir, sofosbuvir/velpatasvir, sofosbuvir/velpatasvir/voxilaprevir, glecaprevir/pibrentasvir.
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- **Medicines used to treat bacterial infections,** including tuberculosis and AIDS-related mycobacterium avium complex: clarithromycin, rifabutin, rifampicin. Your doctor may consider changing your dose or giving you an alternative antibiotic. In addition, your doctor may prescribe a higher dose of [Invented name].
- **Medicines used to treat fungal infections (antifungals):**
 - voriconazole. [Invented name] may reduce the amount of voriconazole in your blood and voriconazole may increase the amount of [Invented name] in your blood. If you take these two medicines together, the dose of voriconazole must be increased and the dose of efavirenz must be reduced. You must check with your doctor first.
 - itraconazole. [Invented name] may reduce the amount of itraconazole in your blood.
 - posaconazole. [Invented name] may reduce the amount of posaconazole in your blood.
- **Medicines used to treat parasitic infections:**
 - praziquantel: [invented name] may reduce the amount of praziquantel in your blood. If you take these two medications together, your doctor may recommend increasing the dose of praziquantel, if needed.
- **Medicines used to treat malaria:**
 - artemether/lumefantrine: Efavirenz may reduce the amount of artemether/lumefantrine in your blood.
 - atovaquone/proguanil: Efavirenz may reduce the amount of atovaquone/proguanil in your blood.
- **Medicines used to treat convulsions/seizures (anticonvulsants):** carbamazepine, phenytoin, phenobarbital. Efavirenz can reduce or increase the amount of anticonvulsant in your blood. Carbamazepine may make Efavirenz less likely to work. Your doctor may need to consider giving you a different anticonvulsant.
- **Medicines used to lower blood fats (also called statins):** atorvastatin, pravastatin, simvastatin. [Invented name] can reduce the amount of statins in your blood. Your doctor will check your cholesterol levels and will consider changing the dose of your statin, if needed.
- **Methadone** (a medicine used to treat opiate addiction): your doctor may recommend an alternative treatment.
- **Metamizole**, a medicine used to treat pain and fever
- **Sertraline** (a medicine used to treat depression): your doctor may need to change your dose of sertraline.
- **Bupropion** (a medicine used to treat depression or to help you stop smoking): your doctor may need to change your dose of bupropion.
- **Diltiazem or similar medicines (called calcium channel blockers which are medicines typically used for high blood pressure or heart problems):** when you start taking [Invented name], your doctor may need to adjust your dose of the calcium channel blocker.
- **Immunosuppressants such as cyclosporine, sirolimus, or tacrolimus** (medicines used to prevent organ transplant rejection): when you start or stop taking [Invented name], your doctor will closely monitor your plasma levels of the immunosuppressant and may need to adjust its dose.
- **Hormonal contraceptive, such as birth control pills, an injected contraceptive (for example, Depo-Provera), or a contraceptive implant (for example, Implanon):** you must also use a reliable

barrier method of contraception (see Pregnancy, breast-feeding and fertility). [Invented name] may make hormonal contraceptives less likely to work. Pregnancies have occurred in women taking efavirenz while using a contraceptive implant, although it has not been established that the efavirenz therapy caused the contraceptive to fail.

- **Warfarin** or acenocoumarol (medicines used to reduce clotting of the blood): your doctor may need to adjust your dose of warfarin or acenocoumarol.
- *Ginkgo biloba* extracts (a herbal preparation)
- **Medicines that impact heart rhythm:**
 - **Medicines used to treat heart rhythm problems** such as flecainide or metoprolol.
 - **Medicines used to treat depression** such as imipramine, amitriptyline or clomipramine.
 - **Antibiotics**, including the following types: macrolides, fluoroquinolones or imidazole.

[Invented name] with food and drink

Taking [Invented name] on an empty stomach, may reduce the undesirable effects. Grapefruit juice should be avoided when taking [Invented name].

Pregnancy and breast-feeding

Women should not get pregnant during treatment with [Invented name] and for **12 weeks thereafter**.

Your doctor may require you to take a pregnancy test to ensure you are not pregnant before starting treatment with [Invented name].

If you could get pregnant while receiving [Invented name], you need to use a reliable form of barrier 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 [Invented name].

Tell your doctor immediately if you are pregnant or intend to become pregnant. If you are pregnant, you should take [Invented name] only if you and your doctor decide it is clearly needed. Ask your doctor or pharmacist for advice before taking any medicine.

Serious birth defects have been seen in unborn animals and in the babies of women treated with efavirenz or a combination medicine containing efavirenz, emtricitabine and tenofovir, during pregnancy. If you have taken [Invented name] or the combination tablet containing efavirenz, emtricitabine, and tenofovir during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child.

Breast-feeding **is not recommended** in women living with HIV because HIV infection can be passed on to the baby in breast milk.

If you are breast-feeding, or thinking about breast-feeding, you **should discuss it with** your doctor **as soon as possible**.

Driving and using machines

[Invented name] contains efavirenz and may cause dizziness, impaired concentration, and drowsiness.

If you are affected, do not drive and do not use any tools or machines.

[Invented name] contains lactose in each 600-mg daily dose.

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 [Invented name]

Always take 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 may need to be increased or decreased if you are also taking certain medicines (see Other medicines and [Invented name]).
- [Invented name] is for oral use. [Invented name] is recommended to be taken on an empty stomach preferably at bedtime. This may make some side effects (for example, dizziness, drowsiness) less troublesome. An empty stomach is commonly defined as 1 hour before or 2 hours after a meal.
- It is recommended that the tablet be swallowed whole with water.
- [Invented name] must be taken every day.
- [Invented name] should never be used alone to treat HIV. [Invented name] must always be taken in combination with other anti-HIV medicines.

Use in children and adolescents

- [Invented name] film-coated tablets are not suitable for children weighing less than 40 kg.
- The dose for children weighing 40 kg or more is 600 mg once daily.

If you take more [Invented name] than you should

If you take too much [Invented name], contact your doctor or nearest emergency department for advice. Keep the medicine container with you so that you can easily describe what you have taken.

If you forget to take [Invented name]

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

If you stop taking [Invented name]

When your [Invented name] 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 have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

When treating HIV infection, it is not always possible to tell whether some of the unwanted effects are caused by [Invented name] or by other medicines that you are taking at the same time, or by the HIV disease itself.

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

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

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. Rash was more common in children than in adults treated with efavirenz.

The nervous system symptoms tend to occur when treatment is first started, but generally decrease in the first few weeks. In one study, nervous system symptoms often occurred during the first 1-3 hours after taking a dose. If you are affected your doctor may suggest that you take [Invented name] at bedtime and on an empty stomach. Some patients have more serious symptoms that may affect mood or the ability to think clearly. Some patients have actually committed suicide. These problems tend to occur more often in those who have a history of mental illness. In addition, 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 <Invented name> therapy. Always notify your doctor immediately if you have these symptoms or any side effects while taking [Invented name].

Tell your doctor if you notice any of the following side effects:

Very common (affects more than 1 user in 10)

- skin rash

Common (affects 1 to 10 users in 100)

- abnormal dreams, difficulty concentrating, dizziness, headache, difficulty sleeping, drowsiness, problems with coordination or balance
- stomach pain, diarrhoea, feeling sick (nausea), vomiting
- itching
- tiredness
- feeling anxious, feeling depressed

Tests may show:

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

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

- 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 inflammation of the liver
- breast enlargement in males
- angry behaviour, mood being affected, seeing or hearing things that are not really there (hallucinations), mania (mental condition characterised by episodes of overactivity, elation or irritability), paranoia, suicidal thoughts, catatonia (condition in which the patient is rendered motionless and speechless for a period)
- whistling, ringing or other persistent noise in the ears
- tremor (shaking)
- flushing

Tests may show:

- increased cholesterol in the blood

Rare (affects 1 to 10 users 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

Not known (frequency cannot be estimated from the available data)

- mental status changes and brain disorder characterised, for example, by seizures and decreased consciousness (encephalopathy)

Reporting 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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

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 [Invented name] contains

- Each [Invented name] film-coated tablet contains 600 mg of the active substance efavirenz.
- The other ingredients of the tablet core are: microcrystalline cellulose, lactose monohydrate, sodium laurilsulfate, croscarmellose sodium, hydroxypropylcellulose, magnesium stearate
- The film coating contains: hypromellose (E464), titanium dioxide (E171), yellow iron oxide (E172) and macrogol (E1521).

What [Invented name] looks like and contents of the pack

[Invented name] 600 mg film-coated tablets are supplied in bottles of 30 tablets.

[Invented name] 600 mg film-coated tablets are also supplied in packs containing 30 or 90 tablets in blisters. Not all pack sizes may be marketed.

Marketing Authorisation Holder

<To be completed nationally>

Manufacturer(s)

<To be completed nationally>

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

Denmark	Efavirenz Medical Valley
Sweden	Efavirenz Medical Valley

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