

FDA-approved patient labeling

Patient Information
INTELENCE® (in-tel-ence)
 etravirine (et-ra-vir-een)
 Tablets

Important: Ask your doctor or pharmacist about medicines that should NOT be taken with INTELENCE®. For more information, read the section “Can INTELENCE® be taken with other medicines?”.

Read this information carefully before you start taking INTELENCE® and each time you renew your prescription, as new information may be available. This leaflet does not take the place of talking with your doctor. You and your doctor should discuss your treatment with INTELENCE® when you start taking it and at regular checkups. You should not change or stop treatment without first talking with your doctor.

What is INTELENCE®?

- **INTELENCE® is a prescription anti-HIV medicine that helps to control HIV (Human Immunodeficiency Virus) infection in adults. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).** INTELENCE® is a type of anti-HIV medicine called a non-nucleoside reverse transcriptase inhibitor (NNRTI).
- INTELENCE® is used with other anti-HIV medicines in patients who are already taking or have taken NNRTI and other anti-HIV medicines and these medicines are not controlling their HIV infection.
- It is important that you remain under the care of your doctor during treatment with INTELENCE®.
- The safety and effectiveness of INTELENCE® have not been studied in children.

INTELENCE® must be taken in combination with other anti-HIV medicines.

How does INTELENCE® work?

- INTELENCE® blocks an enzyme which the virus (HIV) needs in order to make more virus. The enzyme that INTELENCE® blocks is called HIV reverse transcriptase.
- When used with other anti-HIV medicines, INTELENCE® can help:
 - reduce the amount of HIV in your blood. This is called your “viral load”.
 - increase the number of white blood cells called CD4+ (T) cells that help fight off other infections.

Reducing the amount of HIV and increasing the CD4+ (T) cell count may improve your immune system and, as a result, reduce the risk of death or infections that can happen when your immune system is weak (opportunistic infections).

Does INTELENCE® cure HIV or AIDS?

No. INTELENCE® does not cure HIV infection or AIDS. Right now, there is no cure for HIV infection. People taking INTELENCE® may still get opportunistic infections or other conditions that happen with HIV infection. Opportunistic infections are infections that develop because the immune system is weak. Some of the other conditions that can happen with HIV are: pneumonia, herpes virus infection, *Mycobacterium avium* complex (MAC) infections.

Does INTELENCE® reduce the risk of passing HIV to others?

No. INTELENCE® does **not** reduce the risk of passing HIV to others through sexual contact, sharing needles, or being exposed to your blood.

- Always practice safer sex.
- Use latex or polyurethane condoms to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions, or blood.
- Never re-use or share needles.

Ask your doctor if you have any questions on how to prevent passing HIV to other people.

What should I tell my doctor before I take INTELENCE®?

Together with your doctor, you need to decide whether taking INTELENCE® is right for you.

Tell your doctor about all of your medical conditions, including if you:

- have had or currently have liver problems, including hepatitis B or C.
- are pregnant or planning to become pregnant. It is not known if INTELENCE® can harm your unborn baby. You and your doctor will need to decide if taking INTELENCE® is right for you. If you take INTELENCE® while you are pregnant, talk to your doctor about how you can be included in the Antiretroviral Pregnancy Registry.
- are breastfeeding. Do not breastfeed if you are taking INTELENCE®. You should not breastfeed if you have HIV because of the chance of passing HIV to your baby. Talk with your doctor about the best way to feed your baby.

Can INTELENCE® be taken with other medicines?*

Tell your doctor about all the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements, including St. John’s wort (*Hypericum perforatum*). **Some medicines may interact with INTELENCE®.**

- Sometimes serious side effects happen if INTELENCE® is taken with some medicines.
- INTELENCE® should not be taken with some medicines which may lower the amount of INTELENCE® in your blood. This may lead to an increased HIV viral load. Resistance to INTELENCE® or cross resistance to other HIV medicines may develop.

Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine.

Your doctor and your pharmacist can tell you if you can take these medicines with INTELENCE®. Do not start any new medicines while you are taking INTELENCE® without first talking with your doctor or pharmacist. You can ask your doctor or pharmacist for a list of medicines that can interact with INTELENCE®.

Tell your doctor if you take other HIV medicines. INTELENCE® can be combined with most HIV medicines while some HIV medicines are not recommended.

Tell your doctor if you are taking any of the following medicines:

| Type of Drug | Examples of Generic Names (Brand Names) |
|--|---|
| Antiarrhythmics (to treat abnormal heart rhythms) | amiodarone (Cordarone®) bepridil (Vascor®) digoxin (Lanoxin®) disopyramide (Norpace®) flecainide (Tambocor™) lidocaine (Xylocaine®) mexiletine (Mexitil®) propafenone (Rythmol SR®) quinidine (Quinidex®) |
| Anticoagulants (to prevent blood clots) | warfarin (Coumadin®) |
| Anticonvulsants (to treat epilepsy and prevent seizures) | carbamazepine (Tegretol®, Carbatrol®) phenobarbital (Luminal®) phenytoin (Dilantin®, Phenytek®) |
| Antifungals (to treat fungal infections) | fluconazole (Diflucan®) itraconazole (Sporanox®) ketoconazole (Nizoral®) posaconazole (Noxafil®) voriconazole (Vfend®) |
| Anti-infectives (to treat bacterial infections) | clarithromycin (Biaxin®) |
| Antimycobacterials (to treat bacterial infections, including tuberculosis (TB)) | rifabutin (Mycobutin®) rifampin (Rifadin®, Rifater®, Rifamate®) rifapentine (Priftin®) |
| Benzodiazepines (to treat trouble with sleeping and/or anxiety) | diazepam (Valium®) |
| Corticosteroids (to treat inflammation or asthma) | dexamethasone (Decadron®) |
| HMG-CoA Reductase Inhibitors (to lower cholesterol levels) | atorvastatin (Lipitor®) fluvastatin (Lescol®) lovastatin (Advicor®, Altoprev®, Mevacor®) rosuvastatin (Crestor®) simvastatin (Vytorin®, Zocor®) |
| Immunosuppressants | cyclosporine (Sandimmune®, Neoral®) sirolimus (Rapamune®) tacrolimus (Prograf®) |
| Narcotic Analgesic | methadone (Dolophine®) |
| PDE-5 Inhibitors (to treat erectile dysfunction) | sildenafil (Viagra®) vardenafil (Levitra®) tadalafil (Cialis®) |
| Platelet Aggregation Inhibitors (to prevent blood clots) | clopidogrel (Plavix®) |

This is **not** a complete list of medicines that you should tell your doctor about. Know and keep track of all the medicines you take and have a list of them with you. Show this list to all of your doctors and pharmacists any time you get a new medicine. Both your doctor and your pharmacist can tell you if you can take these other medicines with INTELENCE®.

How should I take INTELENCE®?

- **Take INTELENCE® tablets every day exactly as prescribed by your doctor.** The usual dose is two tablets of INTELENCE® two times each day (a total of four tablets each day). It may be easier to remember to take INTELENCE® if you take it at the same time every day. If you have questions about when to take INTELENCE®, your doctor can help you decide which schedule works for you.

- **Take INTELENCE® following a meal.** Do not take INTELENCE® on an empty stomach. INTELENCE® may not work as well if you take it on an empty stomach. The type of food is not important.
- Swallow INTELENCE® tablets whole, with a liquid such as water. **Do not chew the tablets.** If you are unable to swallow the INTELENCE® tablets whole, you may place the tablets in a glass of water. Stir well until the water looks milky, then drink it immediately. Rinse the glass with water several times, and completely swallow the rinse each time to make sure you take the entire dose.
- Do not change your dose or stop taking INTELENCE® without first talking with your doctor. See your doctor regularly while taking INTELENCE®.
- Take all your anti-HIV medicines as prescribed and at the right times of day. This can help your medicines work better and lowers the chance that your medicines will stop working to fight HIV (drug resistance).
- When your supply of INTELENCE® starts to run low, get more from your doctor or pharmacy. It is important not to run out of INTELENCE®. The amount of HIV in your blood may increase if the medicine is stopped even for a short time.
- If you miss a dose of INTELENCE® within 6 hours of the time you usually take it, take your dose of INTELENCE® following a meal as soon as possible. Then, take your next dose of INTELENCE® at the regularly scheduled time. If you miss a dose of INTELENCE® by more than 6 hours of the time you usually take it, wait and then take the next dose of INTELENCE® at the regularly scheduled time.
- Do not double the next dose to make up for a missed dose. Do not take more or less than your prescribed dose of INTELENCE® at any one time. Always take INTELENCE® following a meal.
- If you take too much INTELENCE®, contact your local poison control center or emergency room right away.

What are the possible side effects of INTELENCE®?

Skin rash is a common side effect of INTELENCE®. Rash can be serious and potentially life-threatening. Call your doctor right away if you get a rash. Your doctor will decide if INTELENCE® must be stopped.

Other common side effects of INTELENCE® include tingling or pain in hands or feet and numbness.

As with other anti-HIV medicines, INTELENCE® may cause side effects, including:

- changes in body shape or body fat. These changes can happen in patients taking anti-HIV medicine. The changes may include an increased amount of fat in the upper back and neck, breast, and around the back, chest, and stomach area. Loss of fat from the legs, arms, and face may also happen. The exact cause and long term health effects of these conditions are not known.
- immune reconstitution syndrome. A condition called Immune Reconstitution Syndrome can happen in some patients with advanced HIV infection (AIDS) when HIV treatment is started. Signs and symptoms of inflammation from opportunistic infections that a person has or had may occur as the medicines work to control the HIV infection and strengthen the immune system. Call your doctor right away if you notice any signs or symptoms of an infection after starting INTELENCE® with other anti-HIV medicines.

Tell your doctor right away about these or any other unusual symptoms. If the condition does not go away or worsens, get medical help.

These are not all of the possible side effects with INTELENCE®. For more information, ask your doctor or pharmacist.

How should I store INTELENCE® tablets?

- Store INTELENCE® tablets at room temperature between 59°F to 86°F (15°C to 30°C).
- Keep INTELENCE® in the bottle given to you by your pharmacist.

Keep the bottle tightly closed to protect INTELENCE® from moisture. The bottle contains 3 little pouches of drying agent (desiccants) to keep the tablets dry. Keep the pouches in the bottle. **Do not eat the pouches. Keep INTELENCE® and all medicines out of the reach of children.**

General Advice about INTELENCE®

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use INTELENCE® for a condition for which it was not prescribed. Do not give INTELENCE® to other people even if they have the same condition you have. It may harm them.

This leaflet provides a summary of the most important information about INTELENCE®. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about INTELENCE® that is written for health professionals. For more information, you may also call Tibotec Therapeutics at 1-877-REACH-TT or 1-877-732-2488.

What are the ingredients in INTELENCE®?

Active ingredient: Each tablet contains 100 mg of etravirine.
Inactive ingredients: hypromellose, microcrystalline cellulose, colloidal silicon dioxide, croscarmellose sodium, magnesium stearate and lactose monohydrate



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