

Patient Information**INTELENCE® (in-tel-ence)**
(etravirine) tablets

Important: Ask your doctor or pharmacist about medicines that should not be taken with INTELENCE®. For more information, see the section “What should I tell my doctor before taking INTELENCE®?”.

Read this Patient Information before you start taking INTELENCE® and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. 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 HIV medicine that:**
 - o is used with other HIV medicines to treat HIV (Human Immunodeficiency Virus) infection in adults and children 6 years of age and older. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). INTELENCE® is a type of HIV medicine called a non-nucleoside reverse transcriptase inhibitor (NNRTI).
 - o is used in people who are already taking or have taken NNRTI and other HIV medicines and these medicines are not controlling their HIV infection.
- It is not known if INTELENCE® is safe and effective in children less than 6 years of age.

When used with other HIV medicines, INTELENCE® may:

1. Reduce the amount of HIV in your blood (called “viral load”).
2. Help increase the number of CD4 (T) cells in your blood which help fight off other infections. Reducing the amount of HIV and increasing the CD4 (T) cell count may improve your immune system. This may reduce your risk of death or infections that can happen when your immune system is weak (opportunistic infections).

INTELENCE® does not cure HIV infection or AIDS.

You must stay on continuous HIV therapy to control HIV infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others:

- **Do not share or re-use needles or other injection equipment.**
- **Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.**
- **Do not have any kind of sex without protection.** Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.

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

What should I tell my doctor before taking INTELENCE®?**Before taking INTELENCE® tell your doctor if you:**

- have had or currently have liver problems, including hepatitis B or C.
- have any other medical conditions.

- are pregnant or plan to become pregnant. It is not known if INTELENCE® will harm your unborn baby.

Pregnancy Registry: There is a pregnancy registry for women who take antiviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your doctor about how you can take part in this registry.

- are breastfeeding or plan to breastfeed. Do not breastfeed if you take INTELENCE®. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your doctor about the best way to feed your baby.

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®.**

INTELENCE® may affect the way other medicines work, and other medicines may affect how INTELENCE® works. Taking INTELENCE® and certain other medicines may cause serious side effects. If you take certain medicines with INTELENCE®, then the amount of INTELENCE® in your body may be too low and INTELENCE® may not work to help reduce your HIV viral load. The HIV virus in your body may become resistant to INTELENCE® or other HIV medicines that are like it.

Tell your doctor if you take other HIV medicines. Some HIV medicines should not be taken with INTELENCE®.

Tell your doctor if you take:

- an antiarrhythmic to treat abnormal heart rhythms—amiodarone (Cordarone®, Pacerone®), bepridil (Vasacor®), digoxin (Lanoxin®), disopyramide (Norpace®), flecainide (Tambocor™), lidocaine (LidoPen®, Xylocaine®), mexiletine (Mexitol®), propafenone (Rythmol SR®), quinidine (Duraquin®, Quinaglute®)
- an anticoagulant to prevent blood clots—warfarin (Coumadin®)
- an anti-seizure medicine to treat epilepsy or prevent seizures—carbamazepine (Tegretol®, Tegretol-XR®, Carbatrol®, Equetro®, Teril®, Epitol®), phenobarbital (Luminal®, Solfoton®), phenytoin (Dilantin®, Dilantin-125®, Phenytek®)
- an antifungal to treat a fungal infection—fluconazole (Diflucan®), itraconazole (Onmel®, Sporanox®), ketoconazole (Nizoral®), posaconazole (Noxafil®), voriconazole (Vfend®)
- an anti-infective to treat a bacterial infection—clarithromycin (Biaxin®, Biaxin XL®)
- a medicine to treat malaria—artemether/lumefantrine (Coartem®)
- an antimycobacterial to treat a bacterial infection, including tuberculosis (TB)—rifabutin (Mycobutin®), rifampin (Rifadin®, Rifater®, Rifamate®, Rimactane®), rifapentine (Priftin®)
- a benzodiazepine to treat trouble with sleeping and/or anxiety—diazepam (Diastat®, Valium®)
- a corticosteroid to treat inflammation or asthma—dexamethasone (Decadron®)
- an HMG-CoA reductase inhibitor to lower cholesterol levels—atorvastatin (Caduet®, Lipitor®), fluvastatin (Lescol®), lovastatin (Advicor®, Altoprev®, Mevacor®), pitavastatin (Livalo®), rosuvastatin (Crestor®), simvastatin (Juvissync®, Simcor®, Vytorin®, Zocor®)

- an immunosuppressant to prevent organ transplant rejection—cyclosporine (Gengraf®, Sandimmune®, Neoral®), sirolimus (Rapamune®), tacrolimus (Prograf®)
- a medicine to treat narcotic withdrawal and dependence—buprenorphine (Buprenex®, Butrans®, Subutex®), buprenorphine/naloxone (Suboxone®), methadone (Dolophine®, Methadose®)
- a PDE-5 inhibitor to treat erectile dysfunction and/or pulmonary arterial hypertension—sildenafil (Revatio®, Viagra®), tadalafil (Adcirca®, Cialis®), vardenafil (Levitra®, Staxyn™)
- a platelet aggregation inhibitor to prevent blood clots—clopidogrel (Plavix®)

Ask your doctor or pharmacist if you are not sure if your medicine is one that is listed above.

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®.

How should I take INTELENCE®?

- **Stay under the care of your doctor during treatment with INTELENCE®.**
- **Take INTELENCE® tablets every day exactly as prescribed by your doctor.**
- Your doctor will tell you how many INTELENCE® tablets to take and when to take them. Talk to your doctor if you have questions about when to take INTELENCE®.
- INTELENCE® is taken two times each day.
 - If your child takes INTELENCE®, your doctor will prescribe the right dose based on your child's weight.
- **Always 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.
- Do not change your dose or stop taking INTELENCE® without first talking with your doctor. See your doctor regularly while taking INTELENCE®.
- Swallow INTELENCE® whole, with a glass of water. Do not chew the tablet(s).
- If you are unable to swallow INTELENCE® tablets whole, you may take your dose of INTELENCE® as follows:
 - Step 1: Measure approximately 5 mL (1 teaspoon) of water and pour into a cup.
 - Step 2: Place the tablets in the cup containing 5 mL of water. If needed, add more water to cover the tablets. **Do not put the tablets in other liquids.**
 - Step 3: Stir well until the water looks milky.
 - Step 4: At this step, you may add a small amount of water, orange juice or milk to make it easier to take.
 - Step 5: Drink right away.
 - Step 6: Add more water, orange juice or milk to the cup to rinse the cup several times and completely swallow each time to make sure you take your entire dose of INTELENCE®.

- Avoid using grapefruit juice or warm (more than 104°F or 40°C) or carbonated beverages when taking INTELENCE® tablets.
- 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 take more than your prescribed dose to make up for a missed dose.
- If you take too much INTELENCE®, contact your local poison control center or go to the nearest emergency room right away.

What are the possible side effects of INTELENCE®?

INTELENCE® can cause serious side effects including:

- **Severe skin rash and allergic reactions.** Skin rash is a common side effect of INTELENCE®. Rash can be serious. Call your doctor right away if you get a rash. In some cases, severe rash and allergic reaction may need to be treated in a hospital and may potentially lead to death.

If you get a rash with any of the following symptoms, stop taking INTELENCE® and call your doctor or get medical help right away:

- o hives or sores in your mouth, or your skin blisters and peels
- o trouble swallowing or breathing
- o swelling of your face, eyes, lips, tongue, or throat
- o fever, yellowing of the skin or whites of the eyes, dark urine, or pain on the right side of the stomach-area (abdominal pain).

- **Changes in body fat** can happen in people taking HIV medicines. These changes may include an increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these problems are not known.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Call your doctor right away if you start having any new symptoms after starting your HIV medicine.

In adults, common side effects of INTELENCE® include tingling, numbness, or pain in the hands or feet.

In children, diarrhea is a common side effect of INTELENCE®.

Tell your doctor if you have any side effect that bothers you or that does not go away.

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

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store INTELENCE®?

- Store INTELENCE® tablets at 59°F to 86°F (15°C to 30°C).
- Keep INTELENCE® in the original bottle given to you by your pharmacist. After opening, keep the bottle tightly closed to protect INTELENCE® from moisture.
- The INTELENCE® bottle contains a desiccant packet to help keep your medicine dry (protect it from moisture). The bottle of 25 mg tablets contains 2 desiccant packets. The bottles of 100 mg and 200 mg tablets contain 3 desiccant packets. Keep the desiccant packets in the bottle. **Do not eat the desiccant packets.**

Keep INTELENCE® and all medicines out of the reach of children.

General information 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 summarizes 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 Janssen Products, LP at 1-800-526-7736.

What are the ingredients in INTELENCE®?

Active ingredient: etravirine.

25 mg and 100 mg INTELENCE® tablets contain the following inactive ingredients: hypromellose, microcrystalline cellulose, colloidal silicon dioxide, croscarmellose sodium, magnesium stearate and lactose monohydrate

200 mg INTELENCE® tablets contain the following inactive ingredients: hypromellose, silicified microcrystalline cellulose, microcrystalline cellulose, colloidal silicon dioxide, croscarmellose sodium and magnesium stearate.

This Patient Information has been approved by the U.S. Food and Drug Administration.



Product of Belgium

Finished Product Manufactured by:

Janssen Cilag S.p.A., Latina, IT

Manufactured for:

Janssen Therapeutics, Division of Janssen Products, LP,
Titusville NJ 08560

INTELENCE® is the registered trademark of Tibotec
Pharmaceuticals.

Revised February 2013

© Janssen Pharmaceuticals, Inc. 2008

999350

056574-160715