

PATIENT INFORMATION
INTELENCE® (in-tel-ence)
(etravirine)
tablets

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

What is INTELENCE?

INTELENCE is a prescription medicine that is used in combination with other antiretroviral medicines to treat human immunodeficiency virus-1 (HIV-1) infection in adults and children 2 years of age and older who have taken HIV-1 medicines in the past.

HIV-1 is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

INTELENCE is not recommended for use in children less than 2 years of age.

What should I tell my healthcare provider before taking INTELENCE?

Before taking INTELENCE tell your healthcare provider about all of your medical conditions, including if you:

- have liver problems, including hepatitis B or C.
- are pregnant or plan to become pregnant. Tell your healthcare provider if you become pregnant during treatment with INTELENCE.

Pregnancy Registry: There is a pregnancy registry for people who take INTELENCE during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider 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-1 because of the risk of passing HIV-1 to your baby.
 - INTELENCE can pass to your baby in your breast milk.
 - Talk with your healthcare provider about the best way to feed your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines may interact with INTELENCE. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new medicine.

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with INTELENCE.
- **Do not start a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take INTELENCE with other medicines.

How should I take INTELENCE?

- **Stay under the care of your healthcare provider during treatment with INTELENCE.**
- **Take INTELENCE tablets every day exactly as prescribed by your healthcare provider.**
- Your healthcare provider will tell you how many INTELENCE tablets to take and when to take them. Talk to your healthcare provider if you have questions about when to take INTELENCE.
- Take INTELENCE 2 times each day.
- If your child takes INTELENCE, your healthcare provider 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 healthcare provider.
- Swallow INTELENCE tablets whole, with liquid, such as 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: Add a small amount (approximately 15 mL or 1 tablespoon) of liquid. Water may be used, but adding orange juice or milk rather than water may make it easier to take. Do not use warm (temperature more than 104°F or 40°C) or carbonated beverages.

Step 5: Drink the mixture right away.

Step 6: Add more orange juice, milk, or water to the cup to rinse the cup several times and completely swallow each time to make sure you take your entire dose of INTELENCE.

- It is important that you do not miss or skip doses of INTELENCE during treatment.
- When your supply of INTELENCE starts to run low, get more from your healthcare provider 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 take too much INTELENCE, call your healthcare provider 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 healthcare provider 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 lead to death.

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

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|-------------------------|-----------------------------------|--|
| ○ fever | ○ muscle or joint aches | ○ redness or swelling of the eyes |
| ○ generally ill feeling | ○ blisters or sores in mouth | ○ swelling of the mouth, lips, or face |
| ○ extreme tiredness | ○ blisters or peeling of the skin | ○ problems breathing |

Sometimes allergic reactions can affect body organs, such as your liver. Call your healthcare provider right away if you have any of the following signs or symptoms of liver problems.

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|---|--|
| ○ yellowing of your skin or whites of your eyes | ○ nausea or vomiting |
| ○ dark or tea colored urine | ○ loss of appetite |
| ○ pale colored stools (bowel movements) | ○ pain, aching, or tenderness on the right side of your stomach area |

- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 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 healthcare provider right away if you start having any new symptoms after starting your HIV-1 medicine.
- **Changes in body fat** can happen in people taking HIV-1 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.

The most common side effects of INTELENCE in adults include rash as well as numbness, tingling or pain in the hands or feet.

The most common side effects of INTELENCE in children include rash and diarrhea.

These are not all the possible side effects of INTELENCE.

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 room temperature between 68°F to 77°F (20°C to 25°C).
- Keep INTELENCE in the original bottle.
- 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 the safe and effective use of 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 symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about INTELENCE that is written for health professionals.

What are the ingredients in INTELENCE?

Active ingredient: etravirine.

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

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

Product of Belgium

Finished Product Manufactured by:

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

Or

Janssen Ortho LLC, Gurabo, PR 00778

Manufactured for:

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

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For more information, call Janssen Products, LP at 1-800-526-7736.

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

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