

PART III: CONSUMER INFORMATION

Pr**INTELENCE**[®]
etravirine tablets

This leaflet is Part III of a three-part "Product Monograph" published when INTELENCE[®] was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about INTELENCE[®]. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

INTELENCE[®] is an oral tablet used for the treatment of HIV (Human Immunodeficiency Virus) infection in adults, children and adolescents (6 years to less than 18 years of age). HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). INTELENCE[®] is a type of anti-HIV drug called a non-nucleoside reverse transcriptase inhibitor (NNRTI), otherwise known as a "non-nuke".

INTELENCE[®] does not reduce the risk of passing HIV to others through sexual contact, sharing needles, or being exposed to your blood. For your health and the health of others, it is important to always practice safer sex by using a latex or polyurethane condom or other barrier method to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions, or blood. Never use or share dirty needles.

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

What it does:

INTELENCE[®] blocks HIV reverse transcriptase, an enzyme which the virus needs to multiply. When used with other anti-HIV medicines, INTELENCE[®] reduces the amount of HIV in your blood (called "viral load") and increases your CD4 (T) cell count. HIV infection destroys CD4 (T) cells, which are important to the immune system. The immune system helps fight infection. Reducing the amount of HIV and increasing the CD4 (T) cell count can improve your immune system and, thus, reduce the risk of death or infections that can happen when your immune system is weak (opportunistic infections).

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

INTELENCE[®] does **not** cure HIV infection or AIDS. At present, there is no cure for HIV infection. People taking INTELENCE[®] may still develop infections or other conditions associated with HIV infection. Because of this, it is very important for you to remain under the care of a doctor. Although INTELENCE[®] is not a cure for HIV or AIDS, INTELENCE[®] can help reduce your risks of getting

illnesses associated with HIV infection (AIDS and opportunistic infection) and eventually dying from these conditions.

When it should not be used:

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

Do not take INTELENCE[®]:

- with combinations that contain ombitasvir/paritaprevir/ritonavir (Technivie[®]) and with drugs containing dasabuvir (Holkira Pak[®]) (see "Interactions with this medicine").
- if you are allergic to etravirine or any of the other ingredients in INTELENCE[®] (see "What the nonmedicinal ingredients are").

What the medicinal ingredient is:

The active substance is etravirine. Each 25 mg tablet contains 25 mg of etravirine. Each 100 mg tablet contains 100 mg of etravirine. Each 200 mg tablet contains 200 mg of etravirine.

What the nonmedicinal ingredients are:**INTELENCE[®] 25 mg tablets**

Patients with hereditary problems of lactose intolerance should not take this medicine. The other ingredients are hypromellose, microcrystalline cellulose, colloidal anhydrous silica, croscarmellose sodium, magnesium stearate and lactose monohydrate.

INTELENCE[®] 100 mg tablets

Patients with hereditary problems of lactose intolerance should not take this medicine. The other ingredients are hypromellose, microcrystalline cellulose, colloidal silicon dioxide, croscarmellose sodium, and magnesium stearate and lactose monohydrate.

INTELENCE[®] 200 mg tablets

The other ingredients are hypromellose, silicified microcrystalline cellulose, microcrystalline cellulose, colloidal silicon dioxide, croscarmellose sodium and magnesium stearate.

What dosage forms it comes in:

25 mg tablets
100 mg tablets
200 mg tablets

WARNINGS AND PRECAUTIONS

BEFORE you use INTELENCE[®] talk to your doctor or pharmacist if you:

- have had or currently have liver problems, including hepatitis B and/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 breast-feeding or planning to breast-feed. Do not breast-feed if you are taking INTELENCE®. You should not breast-feed 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.

INTERACTIONS WITH THIS MEDICATION

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*). INTELENCE® and many other medicines can interact. Sometimes serious side effects will happen if INTELENCE® is taken with certain other medicines.

Tell your doctor if you take other anti-HIV medicines, particularly atazanavir, darunavir, didanosine, fosamprenavir, maraviroc, nelfinavir, ritonavir, cobicistat, indinavir, saquinavir, tipranavir, nevirapine, efavirenz, rilpivirine, dolutegravir and delavirdine or any combinations of these medications. INTELENCE® can be combined with some other anti-HIV medicines while other combinations are not recommended.

Do not take the following medications while taking INTELENCE®:

- Do not take anticonvulsants (to treat epilepsy and prevent seizures) such as carbamazepine (Tegretol®), phenobarbital and phenytoin (Dilantin®) while on an INTELENCE® treatment regimen.
- Do not take rifampin (Rifadin®, Rifater®) (to treat bacterial infections) while on an INTELENCE® treatment regimen.
- Do not take elbasvir/grazoprevir (Zepatier®), or simeprevir (Galexos®) (to treat hepatitis C).

Avoid grapefruit or grapefruit juice as this may increase the blood levels of INTELENCE®.

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

Type of Drug **Examples of Generic Names (Brand Names)**

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Antiarrhythmics
(to treat abnormal heart rhythms)

bepidil
disopyramide
digoxin (Lanoxin®)
flecainide
lidocaine
mexiletine
propafenone
quinidine
amiodarone (Cordarone®)

Anticoagulants
(to prevent the clotting of red blood cells)

warfarin (Coumadin®)

Anti-infectives
(to treat bacterial infections)

clarithromycin (Biaxin®)

Antifungals
(to treat fungal infections)

Fluconazole (Diflucan®)
ketoconazole (Nizoral®)
itraconazole (Sporanox®)
voriconazole (Vfend®)
posaconazole (Posanol®)

Antimalarials

artemether/lumefantrine (Coartem®/Riamet®*)

*Coartem® and Riamet® are not marketed in Canada

Antimycobacterials
(to treat bacterial infections)

rifabutin (Mycobutin®)

Benzodiazepines
(to treat anxiety)

diazepam (Valium®),
Diastat®)

Corticosteroids
(to treat inflammation or asthma)

dexamethasone (Decadron®)
fluticasone propionate (Advair Diskus®, Cutivate®, Flonase®, Flovent Diskus®)

Hepatitis C Virus (HCV) Protease Inhibitor
(to treat hepatitis C)

daclastavir (Daklinza®)

HMG-CoA Reductase Inhibitors
(to lower cholesterol)

atorvastatin (Lipitor®)
lovastatin (Mevacor®)
pravastatin (Pravachol®)
simvastatin (Zocor®)

Immunosuppressants
(to prevent organ transplant rejection)

cyclosporine (Sandimmune®, Neoral®)
tacrolimus (Prograf®)
sirolimus (Rapamune®)

<u>Type of Drug</u>	<u>Examples of Generic Names (Brand Names)</u>
Platelet Aggregation Inhibitors (to prevent blood clots)	clopidogrel (Plavix®)
PDE-5 Inhibitors (to treat erectile dysfunction)	sildenafil (Viagra®) vardenafil (Levitra®) tadalafil (Cialis®)

Tell your doctor if you are taking any medicines that you obtained without a prescription.

This is **not** a complete list of medicines that you should tell your doctor that you are taking. 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®. 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®.

PROPER USE OF THIS MEDICATION

Always use INTELENCE® exactly as your doctor has told you. You must check with your doctor if you are not sure.

Usual adult dose:

Take INTELENCE® tablets every day exactly as prescribed by your doctor. The usual dose is 200 mg (one 200 mg tablet or two 100 mg tablets) of INTELENCE®, twice daily *every day*. It may be easier to remember to take INTELENCE® if you take them 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.

You should always take INTELENCE® following a meal. You should not take INTELENCE® on an empty stomach. Taking INTELENCE® on an empty stomach may lessen the effect of INTELENCE®. Follow your doctor's advice on the type of meal you should be taking with INTELENCE®.

Swallow the tablets whole with a liquid such as water. Do not use warm (> 40°C) or carbonated beverages when taking INTELENCE tablet(s). Do not chew the tablets.

If you are unable to swallow the INTELENCE® tablets whole, you may do the following:

- place the tablets in 5 ml (1 teaspoon) of water, or at least enough liquid to cover the medication,
- Stir well until the water looks milky,

- if desired, add more water or alternatively orange juice or milk (do not place the tablets in orange juice or milk without first adding water),
- drink it immediately,
- rinse the glass several times with water, orange juice, or milk and completely swallow the rinse each time to make sure you take the entire dose.

Continue taking INTELENCE® unless your doctor tells you to stop. Take the exact amount of INTELENCE® that your doctor tells you to take, right from the very start. To help make sure you will benefit from INTELENCE®, you must not skip doses or interrupt therapy. If you do not take INTELENCE® as prescribed, the beneficial effects of INTELENCE® may be reduced or even lost.

Instructions for proper use for children and adolescents (6 years to less than 18 years of age) and weighing at least 16 kg.

The doctor will work out the right dose based on the weight of the child. The doctor will inform you exactly how much INTELENCE® the child should take.

Do not stop administering INTELENCE® without talking to the child's doctor. The other HIV medicines used in combination with INTELENCE® should be taken by the child as recommended by the child's doctor.

Overdose:

In case of drug overdose, contact a health care practitioner (doctor), hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If you miss a dose of INTELENCE® by more than 6 hours, wait and then take the next dose of INTELENCE® at the regularly scheduled time. If you miss a dose of INTELENCE® by less than 6 hours, take your missed dose of INTELENCE® immediately, following a meal. Then take your next dose of INTELENCE® at the regularly scheduled time.

If a dose of INTELENCE® is skipped, do not double the next dose. Do not take more or less than your prescribed dose of INTELENCE® at any one time.

Do not stop using INTELENCE® without talking to your doctor first.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all prescription drugs, INTELENCE® can cause side effects. The following is **not** a complete list of side effects reported with INTELENCE® when taken either alone or

with other anti-HIV medicines. Do not rely on this leaflet alone for information about side effects. Your doctor can discuss with you a more complete list of side effects.

The most common side effects include the following:

- Skin rash: The rash is usually mild to moderate. In rare instances, rash can be potentially life-threatening. Children and, in particular, adolescents taking INTELENCE® have a higher chance of developing serious skin rashes. It is therefore important to contact your doctor immediately if you develop a rash. Your doctor will advise you how to deal with your symptoms and decide whether INTELENCE® must be stopped.
- Diarrhea, nausea, abdominal pain, vomiting, heartburn, gas, and inflammation of the stomach
- Fatigue, tingling or pain in hands or feet, numbness, headache, sleeplessness, and anxiety
- Kidney failure, high blood pressure, heart attack, and diabetes
- Night sweats
- Changes in some values of your blood cells or chemistry; These can be seen in the results from blood tests. Your doctor will explain these to you. Examples are low red blood cell count, low blood platelet count, high or abnormal blood fat levels, high cholesterol levels, and high sugar levels.

Other side effects of INTELENCE® which can be serious, include muscle pain, tenderness or weakness.

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 medicines. 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.
- Changes in your immune system (Immune Reconstitution Inflammatory 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, or you could develop an autoimmune disease in which your immune system reacts against your own body (e.g. Graves' disease (which affects the thyroid gland), Guillain-Barré syndrome

(which affects the nervous system) or polymyositis (which affects the muscles) and it may develop at any time, sometimes months later after the start of HIV therapy). Sometimes symptoms can be severe, so if you develop high temperature (fever), joint or muscle pain, redness, rash, swelling, or fatigue or any new symptoms contact your doctor straight away.

Be alert to the following serious side effects which are possible for those taking INTELENCE®.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	<u>Serious skin rash</u> with blistering, mouth ulcers, fever, swelling of face or lips, tongue or parts of the body, shortness of breath			✓
	<u>Liver problems</u> such as hepatitis (liver inflammation) and symptoms such as abdominal pain, persistent vomiting, feeling unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine.		✓	
Uncommon	<u>Diabetes</u> and symptoms such as excessive thirst, excessive urination, excessive eating, unexplained weight loss, poor wound healing, infections		✓	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and
<u>Kidney failure</u> and symptoms such as nausea, loss of appetite and weakness, pass little or no urine, breathlessness		✓	
<u>High blood pressure</u> and symptoms such as headache, dizziness, blurred vision, nausea	✓		

This is not a complete list of side effects. For any unexpected effects while taking INTELENCE®, contact your doctor or pharmacist.

Tell your doctor promptly about these or any other unusual symptoms. If the condition persists or worsens, seek medical attention.

HOW TO STORE IT

Keep out of the reach and sight of children.

Store INTELENCE® tablets at room temperature between 15–30°C. Keep INTELENCE® in the bottle given to you by your pharmacist. Keep the bottle tightly closed in order to protect from moisture.

The bottle of 25 mg tablets contains 2 little pouches (desiccants) and the bottles of 100 mg and 200 mg contain 3 little pouches of drying agent (desiccants) to keep the tablets dry. Keep the pouches in the bottle. Do not eat the pouches. Ask your doctor or pharmacist if you have any questions about storing your tablets.

This medication is prescribed for your particular condition. Do not use it for any other condition or give it to anybody else. Keep INTELENCE® and all of your medicines out of the reach of children. If you suspect that more than the prescribed dose of this medicine has been taken, contact your local poison control centre or emergency room immediately.

This leaflet provides a summary of information about INTELENCE®. If you have any questions or concerns about either INTELENCE® or HIV, talk to your doctor.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance

Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: **Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, Ontario
K1A 0K9**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect® Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For questions, concerns, or the full product monograph go to: <http://www.janssen.com/canada> or contact the manufacturer, Janssen Inc., at: 1-800-567-3331 or 1-800-387-8781

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