

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr**INTELENCE**[®]
etravirine tablets

Read this carefully before you start taking **Intence** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Intence**.

What is Intence used for?

- Intence 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). Intence is a type of anti-HIV drug called a non-nucleoside reverse transcriptase inhibitor (NNRTI), otherwise known as a “non-nuke”.

Intence 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 healthcare professional if you have any questions on how to prevent passing HIV to other people.

How does Intence work?

Intence blocks HIV reverse transcriptase, an enzyme which the virus needs to multiply. When used with other anti-HIV medicines, Intence 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).

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

Intence does **not** cure HIV infection or AIDS. At present, there is no cure for HIV infection. People taking Intence 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 healthcare professional. Although Intence is not a cure for HIV or AIDS, Intence can help reduce your risks of getting illnesses associated with HIV infection (AIDS and opportunistic infection) and eventually dying from these conditions.

What are the ingredients in Intence?

Medicinal ingredient:
etravirine

Non-medicinal ingredients:

Intelence 25 mg tablets:

colloidal anhydrous silica, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, and microcrystalline cellulose.

Intelence 100 mg tablets:

colloidal silicon dioxide, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, and microcrystalline cellulose.

Intelence 200 mg tablets:

colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, microcrystalline cellulose, and silicified microcrystalline cellulose.

Intelence comes in the following dosage forms:

25 mg tablets
100 mg tablets
200 mg tablets

Do not use Intelence if:

- you are taking combinations that contain ombitasvir/paritaprevir/ritonavir (TECHNIVIE) and if you are taking drugs containing dasabuvir (HOLKIRA PAK) (see “**INTERACTIONS WITH THIS MEDICATION**”).
- you are allergic to etravirine or any of the other ingredients in Intelence (see “**What the nonmedicinal ingredients are**”).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Intelence. Talk about any health conditions or problems you may have, including 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 healthcare professional will need to decide if taking Intelence is right for you. If you take Intelence while you are pregnant, talk to your healthcare professional 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 healthcare professional about the best way to feed your baby.
- have hereditary problems of lactose intolerance. You should not take this medicine if you have hereditary problems of lactose intolerance.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Intelence:

Tell your healthcare professional 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 healthcare professional 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:

- anticonvulsants (to treat epilepsy and prevent seizures) such as carbamazepine (TEGRETOL), phenobarbital and phenytoin (DILANTIN) while on an Intelence treatment regimen.
- rifampin (RIFADIN, RIFATER) (to treat bacterial infections) while on an Intelence treatment regimen.
- 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 healthcare professional if you are taking any of the following medicines:

Type of Drug	Examples of Generic Names (Brand Names)	Type of Drug	Examples of Generic Names (Brand Names)
Antiarrhythmics (to treat abnormal heart rhythms)	bepidil disopyramide digoxin (LANOXIN) flecainide lidocaine mexiletine propafenone quinidine amiodarone (CORDARONE)	Corticosteroids (to treat inflammation or asthma)	dexamethasone (DECADRON) fluticasone propionate (ADVAIR DISKUS, CUTIVATE, FLONASE, FLOVENT DISKUS)
Anticoagulants (to prevent the clotting of red blood cells)	warfarin (COUMADIN)	Hepatitis C Virus (HCV) Protease Inhibitor (to treat hepatitis C)	daclastavir (DAKLINZA)
Anti-infectives (to treat bacterial infections)	clarithromycin (BIAXIN)	HMG-CoA Reductase Inhibitors (to lower cholesterol)	atorvastatin (LIPITOR) lovastatin (MEVACOR) pravastatin (PRAVACHOL) simvastatin (ZOCOR)
Antifungals (to treat fungal infections)	Fluconazole (DIFLUCAN) ketoconazole (NIZORAL®) itraconazole (SPORANOX®) voriconazole (VFEND) posaconazole (POSANOL)	Immunosuppressants (to prevent organ transplant rejection)	cyclosporine (SANDIMMUNE, NEORAL) tacrolimus (PROGRAF) sirolimus (RAPAMUNE)
Antimalarials	artemether/lumefantrine (COARTEM/RIAMET*)	Platelet Aggregation Inhibitors (to prevent blood clots)	clopidogrel (PLAVIX)

<u>Type of Drug</u>	<u>Examples of Generic Names (Brand Names)</u>	<u>Type of Drug</u>	<u>Examples of Generic Names (Brand Names)</u>
	*COARTEM and RIAMET are not marketed in Canada		
Antimycobacterials (to treat bacterial infections)	rifabutin (MYCOBUTIN)	PDE-5 Inhibitors (to treat erectile dysfunction)	sildenafil (VIAGRA) vardenafil (LEVITRA) tadalafil (CIALIS)
Benzodiazepines (to treat anxiety)	diazepam (VALIUM, DIASTAT)		

Tell your healthcare professional 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 healthcare professional 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 healthcare professionals any time you get a new medicine. Your healthcare professional 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 healthcare professional. You can ask your healthcare professional for a list of medicines that can interact with Intelence.

How to take Intelence:

Always use Intelence exactly as your healthcare professional has told you. You must check with your healthcare professional if you are not sure

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 healthcare professional'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 water to cover the medication,
- Stir well for about 1 minute until the water looks milky,
- if desired, add up to 30 ml (2 tablespoons) more of 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.

If you mix INTELENCE tablet(s) with water, take this first, before other liquid anti-HIV medicines that you need to take at the same time.

Contact your healthcare professional if you are not able to swallow the entire dose when mixed with water.

If your child needs to take INTELENCE tablet(s) mixed with water, it is very important that the entire dose is taken so that the right amount of medicine enters into the body. If the full dose is not taken, the risk of the virus developing resistance is higher. Contact your healthcare professional if your child is not able to swallow the entire dose when mixed with water, as they may consider giving another medicine to treat your child.

Do not use warm (> 40°C) or carbonated beverages when taking INTELENCE tablet(s).

Usual dose:

Take Intelence tablets every day exactly as prescribed by your healthcare professional.

The usual adult 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 healthcare professional can help you decide which schedule works for you.

Continue taking Intelence unless your healthcare professional tells you to stop. Take the exact amount of Intelence that your healthcare professional 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 benefits 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 healthcare professional will work out the right dose based on the weight of the child. The healthcare professional will inform you exactly how much Intelence the child should take.

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

Overdose:

If you think you, or a person you are caring for, have taken too much Intelence, contact a healthcare professional, 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 healthcare professional first.

What are possible side effects from using Intelence?

These are not all the possible side effects you may have when taking Intelence. If you experience any side effects not listed here, tell your healthcare professional.

The most common side effects include the following:

- Skin rash: The rash is usually mild to moderate.
- 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
- Night sweats
- Changes in some values of your blood cells or chemistry; These can be seen in the results from blood tests. Your healthcare professional 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), autoimmune hepatitis (which affects the liver), 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, abdominal pain, yellowing of the skin and eyes, or fatigue or any new symptoms contact your healthcare professional straight away.

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

Serious side effects and what to do about them				
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help	
	Only if severe	In all cases		
Uncommon				
	<u>Serious skin rash</u> with blistering, peeling skin (particularly around the mouth or eyes), 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.		✓	
	<u>Diabetes</u> and symptoms such as excessive thirst, excessive urination, excessive eating, unexplained weight loss, poor wound healing, infections		✓	
	<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	✓		
	<u>Heart attack</u> or symptoms associated with a heart attack		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store Intelence tablets at room temperature between 15–30°C. Keep Intelence in the bottle given to you by your healthcare professional. 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 healthcare professional 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.

Keep out of the reach and sight of children.

If you want more information about Intelence:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website www.janssen.com/canada, or by contacting the manufacturer at: 1-800-567-3331 or 1-800-387-8781

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