

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using INTELENCE?

INTELENCE contains the active ingredient etravirine. INTELENCE is used to treat adults who are infected by HIV and who have used other anti-HIV medicines before.

For more information, see Section [1. Why am I using INTELENCE?](#) in the full CMI.

2. What should I know before I use INTELENCE?

Do not use if you have ever had an allergic reaction to INTELENCE or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use INTELENCE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with INTELENCE and affect how it works. **Do not combine INTELENCE with medicines listed in Section 2. What should I know before I use INTELENCE?**

There are other medicines that you need to be careful of when taking INTELENCE - See Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use INTELENCE?

- Always take INTELENCE exactly as your doctor has told you. You must check with your doctor if you are not sure.
- The usual dose of INTELENCE is 200 mg twice daily. It is important that you take INTELENCE following a meal. If you take INTELENCE on an empty stomach, only half the amount of INTELENCE is absorbed. Swallow the tablets with a drink such as water. Do not use warm (> 40°C) or carbonated beverages when taking INTELENCE tablet(s).

More instructions can be found in Section [4. How do I use INTELENCE?](#) in the full CMI.

5. What should I know while using INTELENCE?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using INTELENCE. • Always use INTELENCE exactly as your doctor has told you. You must check with your doctor if you are not sure. • Make sure that you always have enough INTELENCE available so that you don't run out. • Be sure to keep all your doctor's appointments so that your progress can be checked • If you are undergoing anaesthesia, tell your anaesthetist that you are taking INTELENCE.
Things you should not do	• Do not stop taking INTELENCE without talking to your doctor first. • Avoid doing things that can spread HIV infection since INTELENCE does not stop you from passing the HIV infection to others.
Driving or using machines	• To drive or use any machines or tools wait until you know how INTELENCE affects you.
Looking after your medicine	• Store below 30°C and in the original bottle. Keep the bottle tightly closed to protect from moisture. • Keep it where children cannot reach it.

For more information, see Section [5. What should I know while using INTELENCE?](#) in the full CMI.

6. Are there any side effects?

The most common side effects of INTELENCE are skin rash, diarrhoea, nausea, abdominal pain, vomiting, heartburn, gas, inflammation of the stomach, fatigue, tingling or pain in hands or feet, numbness, headache, sleeplessness, anxiety, kidney failure, high blood pressure, heart attack, diabetes, night sweats and changes in some values of your blood cells or chemistry.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

INTELENCE®

Active ingredient(s): *etravirine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using INTELENCE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using INTELENCE.**

Where to find information in this leaflet:

1. [Why am I using INTELENCE?](#)
2. [What should I know before I use INTELENCE?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use INTELENCE?](#)
5. [What should I know while using INTELENCE?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using INTELENCE?

INTELENCE contains the active ingredient etravirine.

INTELENCE is a medicine used for the treatment of Human Immunodeficiency Virus (HIV) infection. It belongs to a group of anti-HIV medicines called non-nucleoside reverse transcriptase inhibitors (NNRTIs). INTELENCE works by reducing the amount of HIV in your body. This will improve your immune system and reduce the risk of developing illnesses linked to HIV infection.

INTELENCE is used to treat adults who are infected by HIV and who have used other anti-HIV medicines before. INTELENCE can be used by patients infected with HIV that is resistant to other NNRTIs.

INTELENCE must be taken in combination with other anti-HIV medicines. Your doctor will discuss with you which combination of medicines is best for you.

2. What should I know before I use INTELENCE?

Warnings

Do not use INTELENCE if:

- you are allergic to etravirine, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Do not combine INTELENCE with any of the following medicines:
 - o carbamazepine, phenobarbital, phenytoin (to prevent seizures)
 - o rifampicin and rifapentine (to treat some infections such as tuberculosis)
 - o products that contain St John's wort (*Hypericum perforatum*) (a herbal product used for depression)
 - o elbasvir/grazoprevir (to treat Hepatitis C)

If you are taking any of these, ask your doctor for advice.

This is **not** a complete list of medicines. Therefore, tell your doctor about **all** medicines you take.

There are other medicines that you need to be careful of when taking INTELENCE (see Section [3. What if I am taking other medicines?](#))

Check with your doctor if you:

- have any other medical conditions especially the following:
 - o **Problems with your liver, including hepatitis B and/or C.** Your doctor may need to evaluate how severe your liver disease is before deciding if you can take INTELENCE.
 - o **Symptoms of infection.** In some patients with advanced HIV infection and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response. This improvement enables the body to fight infections that may have been present prior to taking INTELENCE, with no obvious symptoms.
 - o **Changes in body shape or fat.** Redistribution, accumulation or loss of body fat may occur in patients receiving a combination of antiretroviral medicines.
 - o **Rash.** If a rash occurs, it usually appears soon after anti-HIV treatment is started and often disappears within 1 to 2 weeks, even with continued use of the medication. Occasionally a rash can be severe or potentially life-threatening. **Contact your doctor immediately if you get a rash.** Your doctor will advise you how to deal with your symptoms or whether INTELENCE must be stopped.
- take any medicines for any other condition
- take other anti-HIV medicines. Carefully follow your doctor's instructions, on which medicines can be combined.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor immediately if you are pregnant or intend to become pregnant.

Tell your doctor immediately if you are breastfeeding or intend to breastfeed.

HIV infected mothers must not breast-feed, as there is a possibility of infecting the baby with HIV.

During pregnancy and breast-feeding you should not take INTELENCE, unless it is specifically approved by your doctor.

Use in children and adolescents:

- INTELENCE is not for use in children or adolescents, because it has not been sufficiently studied in patients under 18 years of age.

Use in the elderly:

- INTELENCE has only been used in a limited number of patients aged 65 years or older.
- If you belong to this age group, discuss the use of INTELENCE with your doctor.

Take special care with INTELENCE:

- INTELENCE is not a cure for HIV infection. It is part of a treatment reducing the amount of virus in the blood. Talk to your doctor about appropriate precautions to lower the chance of spreading HIV to others.
- People taking INTELENCE can still develop infections or other illnesses associated with HIV. You should continue to keep in regular contact with your doctor and to monitor your health while taking INTELENCE.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

INTELENCE can be combined with most other anti-HIV medicines belonging to another class. However, some combinations are not recommended. In other cases, increased monitoring and/or a change in the dose of the medicine may be needed.

Therefore, always tell your doctor which other anti-HIV medicines you take. Carefully follow your doctor's instructions, on which medicines can be combined.

Also, tell your doctor or pharmacist if you are taking any of the following:

- medicines to treat certain heart disorders, e.g. abnormal heart beat (amiodarone, bepridil, digoxin, disopyramide, flecainide, lignocaine, mexiletine, propafenone or quinidine).
- a medicine used to reduce clotting of the blood (warfarin). Your doctor will have to check your blood.
- medicines to treat fungal infections (fluconazole, itraconazole, ketoconazole, posaconazole, or voriconazole).
- antibiotic (clarithromycin).
- a medicine to treat malaria (artemether/lumefantrine).
- a medicine used to treat some infections such as tuberculosis (rifabutin).
- medicines to treat Hepatitis C (boceprevir or daclatasvir)
- medicines to treat trouble with sleeping and/or anxiety (diazepam).

- dexamethasone (a corticosteroid used in a variety of conditions such as inflammation and allergic reactions).
- cholesterol-lowering medicines (atorvastatin, fluvastatin, lovastatin, pitavastatin, rosuvastatin, or simvastatin).
- immunosuppressants (cyclosporine, sirolimus, or tacrolimus).
- medicines to treat erectile dysfunction (sildenafil, vardenafil, or tadalafil).
- a medicine to prevent blood clots (clopidogrel)

Some medicines may interfere with INTELENCE and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect INTELENCE.

4. How do I use INTELENCE?

How much to take

- The usual dose of INTELENCE is 200 mg twice daily after a meal.
- Follow the instructions provided and use INTELENCE until your doctor tells you to stop.
- Always use INTELENCE exactly as your doctor has told you. You must check with your doctor if you are not sure.
- Make sure that you always have enough INTELENCE available so that you don't run out. For example in case you cannot return home, need to travel or stay in a hospital.

When to take INTELENCE

- If you are taking INTELENCE 100 mg tablets:
 - In the morning, take two 100 milligram INTELENCE tablets, following a meal.
 - In the evening, take two 100 milligram INTELENCE tablets, following a meal.
- If you are taking INTELENCE 200 mg tablets:
 - In the morning, take one 200 milligram INTELENCE tablet, following a meal.
 - In the evening, take one 200 milligram INTELENCE tablet, following a meal.

How to take INTELENCE

- It is important that you take INTELENCE following a meal. If you take INTELENCE on an empty stomach, only half the amount of INTELENCE is absorbed. Follow your doctor's advice on the type of meal you should be taking with INTELENCE.
- Swallow the tablets whole with a glass of liquid such as water. Do not chew the tablets.
- It is possible the tablet may crumble in your mouth; in this case ensure all pieces are swallowed. This does not indicate a problem with the quality of the tablet.
- If you are unable to swallow the INTELENCE tablet(s) whole, you may do the following:

- o place the tablet(s) in 5 mL (1 teaspoon) of water, or at least enough water to cover the medication,
- o stir well for about 1 minute until the water looks milky,
- o 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),
- o drink it immediately.
- o 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 doctor if you are not able to swallow the entire dose when mixed with water.

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

Removing the child resistant cap

The plastic bottle comes with a child resistant cap and should be opened as follows:

- Push the plastic screw cap down while turning it counter clockwise.
- Remove the unscrewed cap.



If you forget to use INTELENCE

If you notice within 6 hours, you must take the tablets immediately. Always take the tablets following a meal. If you notice after 6 hours, then skip the dose and take the next doses as usual. Do not take a double dose to make up for a forgotten dose.

Do not take a double dose to make up for the dose you missed.

If you use too much INTELENCE

If you think that you or anybody else have used too much INTELENCE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia) and 0800 POISON or 0800 764 766 in New Zealand, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using INTELENCE?

Things you should do

- **Keep all your doctor's appointments so your progress can be checked.** Your doctor will want to do some blood, urine and other tests from time to time to check on your progress.
- **Follow up your doctor's instructions about other medicines you should take, and other things you should do.** Ask your doctor or pharmacist if you have any questions.
- **If you are about to be started on any new medicines, tell your doctor or pharmacist that you are taking INTELENCE.**
- **If you become pregnant while taking INTELENCE, tell your doctor immediately.**
- **If you are undergoing anaesthesia, tell your anaesthetist that you are taking INTELENCE.**

Remind any doctor, dentist or pharmacist you visit that you are using INTELENCE.

Things you should not do

- **Do not stop taking INTELENCE without talking to your doctor first.** HIV therapy may increase your sense of well being. Even if you feel better, do not stop taking INTELENCE or your other anti-HIV medicines. Doing so could increase the risk of the virus developing resistance. Talk to your doctor first.

Driving or using machines

To drive or use any machines or tools wait until you know how INTELENCE affects you.

No studies on the effects of INTELENCE on the ability to drive and use machines have been performed. However, you should take into account the possible side effects of INTELENCE before considering driving or using machines.

Looking after your medicine

- Store below 30°C and in the original bottle. Keep the bottle tightly closed in order to protect from moisture.
- The bottle contains 3 little pouches (desiccants) to keep the tablets dry. These pouches should stay in the bottle all the time and are not to be eaten.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

When treating HIV infection, it is not always easy to identify what side effects are caused by INTELENCE, which are caused by other medicines you are taking, or which are INTELENCE caused by the HIV infection itself.

INTELENCE may change some values of your blood chemistry. These can be seen in the results of blood tests. Your doctor will explain these to you.

See the information below and, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Stomach or gut-related: - diarrhoea, nausea, abdominal pain, vomiting, heartburn, gas, inflammation of the stomach Nervous system-related: - fatigue, tingling or pain in hands or feet, numbness, headache, sleeplessness, anxiety Metabolism-related: - kidney failure, diabetes Blood-related: - 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 - high sugar levels Heart-related: - high blood pressure, heart attack Others: - Night sweats - Fever	Speak to your doctor if you have any of these less serious side effects and they worry you.
Skin-related: Skin rash has been reported in patients receiving INTELENCE. Although most rashes are mild and disappear after a while when treatment is continued, a	It is important to consult your doctor if you develop a rash. Your doctor will advise you how to deal with

Less serious side effects	What to do
rash can occasionally be severe or potentially life-threatening.	your symptoms or whether INTELENCE must be stopped.

Serious side effects

Serious side effects	What to do
Signs and symptoms of an allergic reaction: - rash, itching or hives on the skin - shortness of breath, wheezing or trouble breathing Muscle-related: - muscle pain, tenderness or weakness	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Some side effects are typical for combination anti-HIV therapy. These are:

- change in body shape due to fat redistribution. This may include loss of fat from legs, arms and face, increased fat in the abdomen (belly) and other internal organs, breast enlargement and fatty lumps on the back of the neck (buffalo hump). The cause and long-term health effects of these conditions are not known at this time.
- immune reconstitution syndrome. In some patients with advanced HIV infection (AIDS) and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms. Autoimmune disorders may occur many months after the start of treatment.

Tell your doctor if you notice signs or symptoms of infections, such as a fever or rashes. Some people with HIV who have had infections in the past may experience a return of symptoms soon after taking anti-HIV medicines.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What INTELENCE 100 mg tablets contain

Active ingredient (main ingredient)	etravirine
Other ingredients (inactive ingredients)	hypromellose, microcrystalline cellulose, colloidal anhydrous silica, croscarmellose sodium, magnesium stearate and lactose monohydrate
Potential allergens	lactose monohydrate

What INTELENCE 200 mg tablets contain

Active ingredient (main ingredient)	etravirine
Other ingredients (inactive ingredients)	hypromellose, microcrystalline cellulose, colloidal anhydrous silica, croscarmellose sodium, magnesium stearate

Do not take this medicine if you are allergic to any of these ingredients.

What INTELENCE looks like

INTELENCE 100 mg tablets are white to off-white, oval tablet, with "T125" on one side and "100" on the other side. Each plastic bottle contains 120 tablets. The 100 mg tablets are no longer marketed. (AUST R 145797).

INTELENCE 200 mg tablets are white to off-white, biconvex, oblong tablet, with "T200" on one side. Each plastic bottle contains 60 tablets. (AUST R 176557)

Who distributes INTELENCE

JANSSEN-CILAG Pty Ltd
1-5 Khartoum Rd
Macquarie Park NSW 2113 Australia
Telephone: 1800 226 334
NZ Office: Auckland, New Zealand
Telephone: 0800 800 806
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