

INTELENCE[®] Tablets

etravirine

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about INTELENCE tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given INTELENCE against the benefits this medicine is expected to have for you.

If you have any concerns about being given INTELENCE ask your doctor.

Keep this leaflet while you are taking INTELENCE.

You may need to read it again.

What INTELENCE is used for

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.

Ask your doctor if you have any questions about why INTELENCE has been prescribed for you.

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

Before you take INTELENCE

When you must not use it:

Do not take INTELENCE:

- if you are allergic (hypersensitive) to etravirine, or other ingredients of INTELENCE. See Product Description at the end of this leaflet for a list of ingredients.

Do not take INTELENCE:

- if the packaging is torn or shows signs of tampering.
- if the expiry date (month and year) printed on the pack has passed. If you take INTELENCE after the expiry date it may not work.

Do not combine INTELENCE with any of the following medicines:

- carbamazepine, phenobarbital, phenytoin (to prevent seizures)
- rifampicin and rifapentine (to treat some infections such as tuberculosis)
- products that contain St John's wort (*Hypericum perforatum*) (a

herbal product used for depression)

- elbasvir/grazoprevir (to treat Hepatitis C)

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

There are other medicines that you need to be careful of when taking INTELENCE (see Taking other medicines).

Before you start to use it:

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.

You must continue to use appropriate precautions (a condom or other barrier method) to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions or blood.

People taking INTELENCE may still develop infections or other illnesses associated with HIV infection. You must keep in regular contact with your doctor and to monitor your health while taking INTELENCE.

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

Tell your doctor if you have or have had any medical conditions, especially the following:

• **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.

• **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.

• **Changes in body shape or fat.**

Redistribution, accumulation or loss of body fat may occur in patients receiving a combination of antiretroviral medicines.

• **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.

Tell your doctor immediately if you are pregnant or breast-feeding, or intend to become pregnant or breast-feed.

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.

If you have not told your doctor about any of the above, tell them before you start treatment with INTELENCE.

Taking other medicines:

INTELENCE might interact with other medicines. Tell your doctor if you are taking any other medicines, including medicines you can buy without a prescription from a 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:

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

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

Taking INTELENCE

How much INTELENCE to take:

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.

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.

Instructions:

- 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 tablet(s) whole with a glass of liquid such as water. Do not chew the tablet(s).
- 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:

- Place the tablet(s) 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.

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

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.

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.

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.



What do I do if I forget to take 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.

What do I do if I take too much? (overdose):

If you think you or anybody else has taken too much INTELENCE, contact your doctor, pharmacist or the Poisons Information Centre who will advise you what to do.

You can contact the Poisons Information Centre by dialling:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766.

While you are taking INTELENCE

Things you must 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.

Be sure to 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.

Be sure to 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.

Tell any other doctors and pharmacists who are treating you that you are taking INTELENCE. If you are undergoing anaesthesia, tell your anaesthetist that you are taking INTELENCE.

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 have any further questions on the use of this product, ask your doctor.

Things to be careful of

Driving and using machines

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.

Side Effects

Like all medicines, INTELENCE can have side effects. Some of these effects may be serious.

Tell your doctor or pharmacist if you do not feel well while you are being treated with INTELENCE.

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 caused by the HIV infection itself.

The most common side effects are:

- skin rash. The rash is usually mild to moderate. In rare instances, rash can be potentially life-threatening. 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 or whether INTELENCE must be stopped.
- 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.
- 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.

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

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.

If you experience any of these side effects and they worry you, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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.

Other side effects not listed above may also occur in some people.

Product Description

Storage

INTELENCE tablets should be kept out of reach of children, in a location where the temperature stays below 30°C.

INTELENCE tablets should be stored 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.

What it 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.

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

Ingredients

What INTELENCE 100 mg tablets contain

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

The other ingredients are hypromellose, microcrystalline cellulose, colloidal anhydrous silica, croscarmellose sodium, magnesium stearate and lactose monohydrate.

What INTELENCE 200 mg tablets contain

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

The other ingredients are hypromellose, microcrystalline cellulose, colloidal anhydrous silica, croscarmellose sodium and magnesium stearate.

Sponsor

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Registration number

100 mg Tablet: AUST R 145797 (not marketed)

200 mg Tablet AUST R 176557

This leaflet was prepared in:

06 April 2023