

INTELENCE[®] TABLET

Etravirine (100mg)

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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 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.

How Intelence[®] works

Intelence contains an active ingredient, etravirine. 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.

Before you use Intelence[®]

- When you must not use it

Do not take Intelence if you are allergic (hypersensitive) to etravirine or any of the other ingredients of Intelence. These other ingredients are listed in "Product Description".

Pregnancy and Breastfeeding

Tell your doctor immediately if you are pregnant. Pregnant women should not take Intelence unless specifically directed by the doctor.

HIV infected mothers must not breast-feed, as there is a possibility of

infecting the baby with HIV.

- Before you start to use it

Intelence must be taken in combination with other anti-HIV medicines. It is therefore important that you carefully read this leaflet. If you have any further questions about the medicines prescribed, please ask your doctor or pharmacist.

Intelence is not for use in children and adolescents because it has not been sufficiently studied in these patients.

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

Tell your doctor about your situation

Make sure that you check the following points and tell your doctor if any of these apply to you.

- Tell your doctor if you have or have had problems with your liver, including hepatitis B and/or C. Your doctor may evaluate how severe your liver disease is before deciding if you can take Intelence.

- Taking other medicines

Intelence might interact with other medicines. Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In most cases, Intelence can be combined with 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 instruction on which medicines can be combined.

It is not recommended to combine Intelence with any of the following medicines:

- *carbamazepine, phenobarbital,*

phenytoin (medicines to prevent seizures).

- *rifampicin and rifapentine* (medicines to treat some infections such as tuberculosis).
- products that contain St John's wort (*Hypericum perforatum*) (a herbal product used for depression).
- *simeprevir* (medicine to treat hepatitis C infection).

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

The effects of Intelence or other medicine might be influenced if you take Intelence together with any of the following medicines. Tell your doctor if you take:

- *amiodarone, bepridil, digoxin, disopyramide, flecainide, lidocaine, mexiletine, propafenone or quinidine* (medicines 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.
- *itraconazole, ketoconazole, or posaconazole* (medicines 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).
- *diazepam* (medicines to treat trouble with sleeping and/or anxiety).
- *dexamethasone* (a corticosteroid used in a variety of conditions such as inflammation and allergic reactions).
- *daclatasvir* (medicines to treat hepatitis C infection)
- *atorvastatin, fluvastatin, lovastatin, pitavastatin, rosuvastatin, or simvastatin* (cholesterol-lowering medicines).
- *cyclosporine, sirolimus, or tacrolimus* (immunosuppressants).
- *sildenafil, vardenafil, or tadalafil* (medicines to treat impotence and/or pulmonary arterial hypertension, high blood pressure (hypertension) in the pulmonary artery, the blood vessel that carries blood from the heart to the lungs).

How to use Intelence®**- How much to use**

The usual dose of Intelence is 200 milligrams twice a day.

Always take Intelence exactly as your doctor has told you. You should check with your doctor if you are not sure.

Swallow the Intelence tablet(s) whole with a glass of water. Do not chew the tablet(s).

- 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 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.
- 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.

- When to use it

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.

- How long to use it

Continue taking Intelence for as long as your doctor recommends.

- If you forget to use it

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

- If you use too much (overdose)

Contact your doctor or pharmacist immediately.

While you are using it**- Things you must do**

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.

Intelence is not a cure for HIV infection. It is part of a treatment reducing the amount of virus in the blood. Intelence does not reduce the risk of passing HIV to others through sexual contact or blood

contamination. Therefore, 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.

Tell your doctor if you develop a 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. Please 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.

- Things you must not do

Do not stop using 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.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

- 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.

Tell your doctor if you notice changes in body shape or fat. A gain, loss or redistribution of body fat may occur if you take a combination of anti-HIV medicines.

Tell your doctor immediately if you notice any symptoms of infection or

inflammation. In some patients with advanced HIV infection, signs and symptoms of infection or inflammation may occur after anti- HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response.

Side effects

Like any medicine, Intelence can cause side effects, although not everybody gets them.

Very common side effects (affects 1 or more than 1 user in 10)

- 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.

Common side effects (affects 1 to 10 users in 100)

- 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
- changes in body shape or fat
- 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.

Some side effects are typical for anti-HIV medicines. These include immune reconstitution inflammatory 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, including Intelence. In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking

medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI)

Storage and Disposal of Intelence®

- Storage
Keep out of the reach and sight of children.

Do not store above 30°C.

Do not use Intelence after the expiry date, which is stated on the carton and on the bottle after EXP. The expiry date refers to the last day of that month.

Intelence tablets should be stored in the original bottle. Keep the bottle tightly closed in order to protect from moisture. The bottles of 100 mg tablets contain 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.

- Disposal
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like
White to off-white, oval tablet, with "T125" on one side and "100" on the other side.

A plastic bottle containing 120 tablets and 3 pouches to keep the tablets dry.

- Ingredients
- Active ingredient

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

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

- MAL number
MAL20091947AZ

Manufacturer

Janssen-Cilag S.p.A.
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Product Registration Holder

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