

เอกสารกำกับยาสำหรับผู้ป่วยฉับภาษาอังกฤษ

INTELENCE® 200 mg tablets

Active substance: etravirine

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What INTELENCE is and what it is used for
2. Before you take INTELENCE
3. How to take INTELENCE
4. Possible side effects
5. How to store INTELENCE
6. Further information

1. WHAT INTELENCE IS AND WHAT IT IS USED FOR

What is INTELENCE?

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.

What is it used for?

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. BEFORE YOU TAKE INTELENCE

INTELENCE must be taken in combination with other anti-HIV medicines. It is therefore important that you carefully read the package leaflets that are provided with these medicines. If you have any further questions about the medicines prescribed, please ask your doctor or pharmacist.

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 section 6.

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 may still develop infections or other illnesses associated with HIV infection. You must keep in regular contact with your doctor.

INTELENCE is not for use in children less than 18 years of age, 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 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.
- 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.
- 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.

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.

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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)
- *elbasvir/grazoprevir, simeprevir* (medicines 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 erectile dysfunction and/or pulmonary arterial hypertension).
- *clopidogrel* (a medicine to prevent blood clots).

Taking INTELENCE with food and drink

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 water. If you are unable to swallow the INTELENCE tablets whole, you may place the tablets in water. Please follow the instructions in section 3 'HOW TO TAKE INTELENCE'.

Pregnancy and breast-feeding

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.

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.

3. HOW TO TAKE INTELENCE

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

Instructions for proper use for adults

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

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.

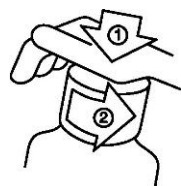
Instructions for taking INTELENCE for all patients

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 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.

If you take more INTELENCE than you should

Contact your doctor or pharmacist immediately.

If you forget to take INTELENCE

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.

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.

4. POSSIBLE SIDE EFFECTS

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

Very common side effects (affects 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.

Uncommon side effects (affects 1 to 10 users in 1,000)

- chest pain/pressure, irregular heart rhythm
- loss of skin sensibility, drowsiness, seizures, loss of memory, fainting, disturbance in attention, sleepiness, trembling
- blurred vision, dizziness
- difficulty breathing
- distension of the abdomen, inflammation of the pancreas (pancreatitis), constipation, dry mouth, vomiting blood, retching, mouth inflammation
- itching, excessive sweating, dry skin, swelling of the face and/or throat
- decrease of appetite
- sluggishness
- allergic reactions (hypersensitivity), symptoms of infection (for example enlarged lymph nodes and fever)
- liver problems such as inflammation of the liver (hepatitis)
- swelling of breasts in men
- sleep disorders, abnormal dreams, confusion, disorientation, nervousness
- change in body shape associated with fat redistribution.

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Frequency not known (cannot be estimated from the available data)

- severe hypersensitivity reactions characterised by rash accompanied by fever and organ inflammation such as hepatitis.
- muscle pain, tenderness or weakness. These muscle disorders can be serious.

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.

5. HOW TO STORE INTELENCE

Keep out of the reach and sight of children.

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 bottle of 200 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.

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.

6. FURTHER INFORMATION

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, silicified microcrystalline cellulose, microcrystalline cellulose, colloidal anhydrous silica, croscarmellose sodium and magnesium stearate.

Name: INTELENCE® (etravirine, tablets) 200 mg

What INTELENCE 200 mg tablets look like and contents of the pack

White to off-white, biconvex, oblong tablet, with "T200" on one side.

A plastic bottle containing 60 tablets and 3 pouches to keep the tablets dry.

Manufactured by

Janssen-Cilag S.p.A., Latina, Republic of Italy

Marketing Authorization Number

1C 75/58(NC) - INTELENCE® 200 mg tablets

Date of Authorization

24 July 2015 - INTELENCE® 200 mg tablets

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Imported by

Janssen-Cilag Ltd., Bangkok, Thailand

To report Suspected Adverse Reactions, please contact us at aepqcjacth@its.jnj.com

For any product information, please contact us at medinfosea@its.jnj.com

Warnings according to Ministry of Public Health announcement

This product can cause severe liver toxicity

Please see full prescribing information at <https://ndi.fda.moph.go.th>