

Package leaflet: Information for the user

INTELENCE 200 mg tablets etravirine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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2. What you need to know before you take INTELENCE
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1. What INTELENCE is and what it is used for

INTELENCE contains the active substance etravirine. INTELENCE belongs to a group of anti-HIV medicines called non-nucleoside reverse transcriptase inhibitors (NNRTIs).

INTELENCE is a medicine used for the treatment of Human Immunodeficiency Virus (HIV) infection. INTELENCE works by reducing the amount of HIV in your body. This will improve your immune system and reduces the risk of developing illnesses linked to HIV infection.

INTELENCE is used in combination with other anti-HIV medicines to treat adults and children 2 years of age and older who are infected by HIV and who have used other anti-HIV medicines before.

Your doctor will discuss with you which combination of medicines is best for you.

2. What you need to know before you take INTELENCE

Do not take INTELENCE

- if you are allergic to etravirine or any of the other ingredients of this medicine (listed in section 6)
- if you are taking elbasvir/grazoprevir (a medicine to treat hepatitis C infection).

Warnings and precautions

Talk to your doctor or pharmacist before taking INTELENCE.

INTELENCE is not a cure for HIV infection. It is part of a treatment reducing the amount of virus in the blood. You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your physician the precautions needed to avoid infecting other people.

Elderly

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

Weight and increased blood lipids and glucose

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Bone problems

Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index, among others, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms please inform 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 with INTELENCE is started and often disappears within 1 to 2 weeks, even with continued use of the medicine. Rarely, during INTELENCE treatment, you can experience severe skin rash with blisters or peeling skin, particularly around the mouth or eyes or hypersensitivity reaction (allergic reaction including rash and fever but also swelling of the face, tongue or throat, difficulty in breathing or swallowing) which could be potentially life-threatening. Please contact your doctor immediately if you experience these symptoms. Your doctor will advise you how to deal with your symptoms and whether INTELENCE must be stopped. If you have stopped treatment due to a hypersensitivity reaction, you should not restart therapy with INTELENCE.
- 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 immediately if you notice any **symptoms of infections**. 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, enabling the body to fight infections that may have been present with no obvious symptoms.
- 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 you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.

Children and adolescents

Do not give this medicine to children less than 2 years of age and weighing less than 10 kg because the potential benefits and risks have not been established.

Other medicines and INTELENCE

INTELENCE might interact with other medicines. Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

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. Furthermore, it is important that you carefully read the package leaflets that are provided with these medicines. Follow your doctor's instruction carefully on which medicines can be combined.

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

- tipranavir/ritonavir, efavirenz, nevirapine, rilpivirine, indinavir, atazanavir/cobicistat, darunavir/cobicistat (anti-HIV medicine)
- carbamazepine, phenobarbital, phenytoin (medicines to prevent seizures)
- rifampicin, because it is contraindicated with boosted protease inhibitors, 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)
- daclatasvir (a medicine to treat hepatitis C infection).

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

The effects of INTELENCE or other medicines might be influenced if you take INTELENCE together with any of the following medicines. The dosages of some medicines might need to be changed since their therapeutic effect or side effects may be influenced when combined with INTELENCE. Tell your doctor if you take:

- dolutegravir, maraviroc, amprevanir/ritonavir and fosamprenavir/ritonavir (anti-HIV medicine)
- amiodarone, bepridil, digoxin, disopyramide, flecainide, lidocaine, mexiletine, propafenone and 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
- fluconazole, itraconazole, ketoconazole, posaconazole, voriconazole (medicines to treat fungal infections)
- clarithromycin, rifabutin (antibiotics)
- artemether/lumefantrine (a medicine to treat malaria)
- 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)
- atorvastatin, fluvastatin, lovastatin, rosuvastatin, simvastatin (cholesterol-lowering medicines)
- cyclosporine, sirolimus, tacrolimus (immunosuppressants – medicines used to dampen down your immune system)
- sildenafil, vardenafil, tadalafil (medicines to treat erectile dysfunction and/or pulmonary arterial hypertension)
- clopidogrel (a medicine to prevent blood clots).

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

Do not drive or operate machines if you feel sleepy or dizzy after taking your medicines.

INTELENCE contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. How to take INTELENCE

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Use in adults

The recommended dose of INTELENCE is one tablet twice a day.

In the morning, take one 200 milligram INTELENCE tablet, following a meal.

In the evening, take one 200 milligram INTELENCE tablet, following a meal.

Use in children and adolescents 2 years of age and older and weighing at least 10 kg

The doctor will work out the right dose based on the weight of the child.

The doctor will inform you exactly how much INTELENCE the child should take.

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 medicine,
- 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 directly in orange juice or milk),
- 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 a liquid, 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 a liquid.

If your child needs to take INTELENCE tablet(s) mixed with a liquid, it is very important that he/she takes the entire dose 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 doctor if your child is not able to swallow the entire dose when mixed with a liquid, as they may consider giving another medicine to treat your child.

Do not use warm (40°C and above) 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. The most frequent side effects of INTELENCE are rash, diarrhoea, nausea, and headache (see section '4. Possible side effects').

If you forget to take INTELENCE

If you notice **within 6 hours of the time you usually take INTELENCE**, you must take the tablet as soon as possible. Always take the tablet following a meal. Then take the next dose as usual. 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 vomit less than 4 hours after taking INTELENCE, take another dose following a meal. If you vomit more than 4 hours after taking INTELENCE, then you do not need to take another dose until your regularly scheduled dose.

Contact your doctor if you are uncertain about what to do if you miss a dose or vomit.

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.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The frequency rate of the side effects associated with INTELENCE is given below.

Very common side effects (may affect more than 1 in 10 people)

- skin rash. The rash is usually mild to moderate. In rare instances, very serious rash has been reported which 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 and whether INTELENCE must be stopped;
- headache;
- diarrhoea, nausea.

Common side effects (may affect up to 1 in 10 people)

- allergic reactions (hypersensitivity);
- diabetes, decrease of appetite;
- anxiety, sleepiness, sleeplessness, sleep disorders;
- tingling or pain in hands or feet, numbness, loss of skin sensibility, loss of memory tiredness;
- blurred vision;
- kidney failure, high blood pressure, heart attack, shortness of breath when exercising;
- vomiting, heartburn, abdominal pain, distension of the abdomen, inflammation of the stomach, flatulence, constipation, mouth inflammation, dry mouth;
- night sweats, itching, dry skin;
- Change in some values of your blood cells or chemistry. These can be seen in the results of blood and/or urine tests. Your doctor will explain these to you. Examples are: low red blood cells.

Uncommon side effects (may affect up to 1 in 100 people)

- decreased number of white blood cells;
- symptoms of infection (for example enlarged lymph nodes and fever);
- abnormal dreams, confusion, disorientation, nervousness, nightmares;
- drowsiness, trembling, fainting, seizures, disturbance in attention;
- dizziness, sluggishness;
- angina, irregular heart rhythm;
- difficulty breathing;
- retching, inflammation of the pancreas, vomiting blood;
- liver problems such as hepatitis, enlarged liver;
- excessive sweating, swelling of the face and/or throat;
- swelling of breasts in men.

Rare side effects (may affect up to 1 in 1,000 people)

- stroke;
- severe skin rash with blisters or peeling skin, particularly around the mouth or eyes; this may occur in children and adolescents more frequently than in adults.

Very rare side effects (may affect up to 1 in 10,000 people)

- severe hypersensitivity reactions characterised by rash accompanied by fever and organ inflammation such as hepatitis.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly.

In the United Kingdom (Northern Ireland), you can also report side effects directly via the Yellow Card Scheme at <https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store

In Ireland, you can also report side effects directly via:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store INTELENCE

Keep this medicine out of the sight and reach of children.

Do not use this medicine 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.

Do not use after 6 weeks of first opening the bottle.

INTELENCE tablets should be stored in the original bottle and 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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What INTELENCE contains

- The active substance is etravirine. Each 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.

What INTELENCE looks like and contents of the pack

This medicinal product is presented as 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.

Marketing Authorisation Holder

Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium

Manufacturer

Janssen-Cilag SpA, Via C. Janssen, 04100 Borgo San Michele, Latina, Italy

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom (Northern Ireland)

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This leaflet was last revised in March 2021.

Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu/>.