PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

Schedule 4

INTELENCE 100MG TABLET

Etravirine

Contains sugar: Lactose monohydrate 160 mg

Read all of this leaflet carefully before you are given INTELENCE

Keep this leaflet. You may need to read it again.

- INTELENCE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What INTELENCE is and what it is used for
2. What you need to know before you take INTELENCE
3. How to take INTELENCE
4. Possible side effects
5. How to store INTELENCE
6. Contents of the pack and other information

1. What INTELENCE is and what it 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

INTELENCE is used:

- INTELENCE is used to treat adults and children of at least 2 years of age and weighing at least 30 kg who are infected by HIV and who are resistant to anti-HIV medicines used before.
- 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 you need to know 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 hypersensitive (allergic) to etravirine or any of the other ingredients of INTELENCE (listed in section 6).

Warnings and precautions

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. 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.
- INTELENCE is not for use in children less than 2 years of age or weighing less than 30 kg.
- 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.

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 infections or inflammation**. 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.

Children

INTELENCE is not for use in children less than 2 years of age and weighing less than 30 kg.

Other medicines and INTELENCE

INTELENCE might interact with other medicines. Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional 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. Follow your doctor's instruction carefully on which medicines can be combined.

You should not use INTELENCE together with any of the following medicines:

- carbamazepine, phenobarbital, phenytoin (medicines to prevent seizures)
- rifampicin and rifapentine (medicines to treat tuberculosis)
- products that contain St John's wort (*Hypericum perforatum*) (an herbal product used for depression)
- elbasvir/grazoprevir, simeprevir (medicines to treat hepatitis C infection)
- itraconazole, ketoconazole, or posaconazole, fluconazole or voriconazole (medicines to treat fungal infections)

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. Tell your doctor if you take:

- amiodarone, bepridil, 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.
- clarithromycin (an antibiotic)
- 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)
- daclatasvir (medicines to treat hepatitis C infection)
- cyclosporine, sirolimus, tacrolimus (immunosuppressants)
- sildenafil, vardenafil, tadalafil (medicines to treat erectile dysfunction)
- clopidogrel (a medicine to prevent blood clots)

INTELENCE with food and drink ~~and alcohol~~

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. Please follow the instructions in HOW TO TAKE INTELENCE.

Pregnancy and Breastfeeding

Tell your doctor immediately if you are pregnant. Pregnant women should not take INTELENCE.

HIV infected mothers must not breast feed, as there is a possibility of infecting the baby with HIV and as the safety in babies is not known.

Always tell your healthcare provider if you are taking any other medicine. If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before taking INTELENCE.

Driving and using machines

Some patients may experience tiredness, dizziness or drowsiness during treatment with INTELENCE. Do not drive or operate machinery if you feel tired, dizzy or drowsy while taking INTELENCE.

Important information about some of the ingredients in INTELENCE

INTELENCE contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Patients with the rare hereditary conditions of lactose / fructose or galactose intolerance should not take INTELENCE.

3. How to take INTELENCE

Do not share INTELENCE prescribed for you with others.

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

Instructions for proper use

The usual dose of INTELENCE is two 100 milligram tablets twice a day.

In the morning, take two 100 milligram INTELENCE tablets, after a meal.

In the evening, take two 100 milligram INTELENCE tablets, after a meal.

Instructions for proper use for children 2 years of age and older and weighing at least 30 kg

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

Do not stop administering INTELENCE without talking to the child's doctor.

The other HIV medicines used in combination with INTELENCE should be taken by the child as recommended by the child's doctor.

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. Do not chew the tablets.

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.

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.

If your child needs to take INTELENCE tablet(s) mixed with water, it is very important that the entire dose is taken so that the right amount of medicine enters 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 water, as they may consider giving another medicine to treat your child.

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. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of 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 stop using INTELENCE without talking to your doctor first

HIV therapy may increase your sense of wellbeing. 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

INTELENCE can cause side effects

If any of the following happens, stop taking / using INTELENCE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- skin rash. The rash is usually mild to moderate. In rare instances, rash can be potentially life threatening. A skin rash might also be a symptom of a rare, severe situation. 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.

- muscle pain, tenderness or weakness
- chest pain
- angina
- changes in the way your heart beats, for example, if you notice it beating faster
- difficulty breathing
- signs of recurrent infections such as fever or sore throat
- swelling of the face and / or throat

These are all serious side effects. You may need urgent medical attention.

Frequent side effects

- headache,
- diarrhoea, nausea
- 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
- changes in body shape or fat
- 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.

Less frequent side effects

- decreased number of white blood cells
- 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), 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
- 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
- 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 combination anti-HIV therapy:

- 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 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.

Not all side effects reported for INTELENCE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking INTELENCE, please consult your healthcare provider for advice.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via “6.04 Adverse Drug Reaction Reporting Form” found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/index/8.

By reporting side effects, you can help provide more information on the safety of INTELENCE tablets.

5 How to store INTELLENCE

Store at or below 30 °C in the original bottle.

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 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.

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.

Do not store in a bathroom.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

6 Contents of the pack and other information

What INTELENCE contains:

- The active ingredient in each tablet of INTELENCE is 100 mg of etravirine
- The other ingredients are: colloidal anhydrous silica, croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose
- Contains sugar: Lactose monohydrate 160 mg

What INTELENCE looks like and contents of the pack

120 tablets are packed in a white, high density polyethylene container sealed with a polypropylene child resistant closure with an induction seal liner, together with 3 desiccant silica gel pouches and a leaflet.

IDENTIFICATION OF INTELENCE

White to off-white, oval tablet, debossed with “T125” on one side and “100” on the other side.

Holder of certificate of registration

JANSSEN PHARMACEUTICA (Pty.) Ltd.

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Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.