etravirine (Intelence)

WHAT IS ETRAVIRINE?

Etravirine, also known as ETR (brand name Intelence), is a drug used as part of antiretroviral therapy (ART). The FDA approved etravirine in 2008 as an antiretroviral drug (ARV) for people with HIV infection. Etravirine is manufactured by Janssen Therapeutics.

Etravirine is a type of drug called a non-nucleoside reverse transcriptase inhibitor (NNRTI). NNRTIs bind to and block reverse transcriptase (an HIV enzyme). HIV uses reverse transcriptase to convert its RNA into DNA (reverse transcription). Blocking reverse transcriptase and reverse transcription prevents HIV from replicating.

When used in combination with other ARVs to treat HIV infection, etravirine may help:

- Reduce the amount of HIV in your blood. This is called viral load.
- Increase the number of CD4 cells in your blood that help fight off other infections.

Reducing the amount of HIV and increasing the CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting opportunistic infections (OIs) that can happen when your immune system is weak. Read more about viral suppression.

Etravirine does not cure HIV infection or AIDS. You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

WHO SHOULD TAKE ETRAVIRINE?

Etravirine is a prescription HIV medicine used in combination with other ARVs to treat HIV infection in adults and children 2 years of age and older who have taken HIV medicines in the past. The safety and effectiveness of etravirine has not been established in children under 2 years of age. Etravirine has not been carefully studied in the elderly (65 years of age and older).

All people with HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. Read more about U.S. ART guidelines.

WHO SHOULD NOT TAKE ETRAVIRINE?

Do not take etravirine if you are currently taking the following medications:

- Anti-seizure medicines: carbamazepine, phenobarbital, phenytoin
- Tuberculosis (TB) medicines: rifampin, rifapentine
- Hepatitis C virus (HCV) medicines: elbasvir, grazoprevir, simeprevir
- Herbal product: St John's Wort (*Hypericum perforatum*)
- Other NNRTIs

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any of these medicines in the past 4 weeks, talk to your healthcare provider or pharmacist before starting treatment with etravirine.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING ETRAVIRINE?

Before you take etravirine, tell your healthcare provider about all of your medical conditions, and in particular if you have liver problems, including hepatitis B virus (HBV) or HCV infection.

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with etravirine. There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. Read more about pregnancy and HIV.

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with etravirine. Etravirine can pass to your baby in your breastmilk. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. Read more about HIV drug resistance.

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS ETRAVIRINE TAKEN?

Etravirine is taken by mouth as a tablet. The recommended dosage of etravirine for adults is 400 mg daily taken as either one 200 mg tablet or two 100 mg tablets twice daily, in combination with other ARVs. The recommended dosage in children varies based on the child's weight and age. Your healthcare provider will determine the correct dosage.

Take etravirine at the same time each day following a meal. Do not take etravirine on an empty stomach. Etravirine may not work as well if you take it on an empty stomach.

You need to take etravirine in combination with other ARVs. Your healthcare provider will tell you what medicines to take and how to take them.

WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary side effects such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of etravirine in adults are rash and numbness/tingling/pain in the hands or feet. The most common side effects of etravirine in children are rash and diarrhea.

Etravirine can cause serious side effects including:

Severe skin rash and allergic reactions. Skin rash is a common side effect of etravirine. The risk of getting a skin rash is higher in people assigned female at birth. Rarely, rash can be severe and may lead to death. Severe skin rash with blisters or peeling skin, including the area around the mouth or eyes, may happen more frequently in children less than 18 years of age who take etravirine in combination with other ARVs than in adults. Call your healthcare provider right away if a rash develops; severe cases may need to be treated in a hospital. If you get a rash with any of the following symptoms, stop taking etravirine and call your healthcare provider or get medical help right away:

- Fever
- Generally feeling ill
- Extreme tiredness
- Muscle or joint aches
- Blisters or sores in mouth
- Blisters or peeling of the skin
- Redness or swelling of the eyes
- Swelling of the mouth, lips, or face
- Problems breathing

Liver problems. Sometimes allergic reactions can affect body organs, such as your liver. Call your healthcare provider right away if you have any of the following signs or symptoms of liver problems:

- Yellowing of your skin or whites of your eyes
- Dark or "tea colored" urine
- Pale colored stools (bowel movements)
- Nausea or vomiting
- Loss of appetite
- Pain, aching, or tenderness on the right side of your stomach area

Immune Reconstitution Inflammatory Syndrome (IRIS). IRIS is a side effect that can happen when you start taking HIV medications. Your immune system might get stronger and begin to fight infections that have been hidden in your body for a long time. This may result in an inflammatory response which may require further evaluation and treatment. Tell your healthcare provider right away if you experience any new symptoms after starting etravirine.

Changes in body fat. Changes in body fat distribution or accumulation have happened in some people taking HIV medicines, including an increased amount of fat in the upper back and neck (buffalo hump), in the breasts, and around the trunk. Loss of fat from the legs, arms, and face may also happen. The cause and long-term health effects of these body fat changes are not known.

These are not all the possible side effects of etravirine. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW DOES ETRAVIRINE REACT WITH OTHER DRUGS?

All ARVs can interact with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take etravirine with other medicines.

See above for a list of medicines that should not be taken with etravirine.

MORE INFORMATION

Visit the Intelence website

Visit the Intelence healthcare professional website

Download the full Prescribing Information

Download the Patient Information leaflet

Visit the Janssen CarePath website for Intelence

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