

maraviroc (Selzentry)

WHAT IS MARAVIROC?

Maraviroc, also known as MVC (brand name Selzentry in the U.S. and Celsentri elsewhere) is a drug used as part of <u>antiretroviral therapy (ART)</u>. The FDA approved maraviroc in 2007 as an <u>antiretroviral drug (ARV)</u> for people with HIV infection. Maraviroc is manufactured by <u>ViiV Healthcare</u>.

Maraviroc is a CCR5 antagonist. CCR5 antagonists are a class of drugs that block the CCR5 coreceptor on the surface of certain immune cells, such as CD4 cells. When HIV infects a cell, it attaches to the outside of the cell. It uses molecules on the surface of the CD4 cell to attach to the cell before fusing with it. Maraviroc blocks the receptor called a CCR5 molecule. When maraviroc blocks this receptor, HIV cannot infect that cell.

The preference of HIV for certain types of attachment molecules is called tropism. Maraviroc only works against HIV that uses CCR5 to enter the CD4 cell. Before people are prescribed maraviroc, they must take a tropism test to make sure that their virus uses the CCR5 receptor.

CCR5 antagonists are part of a larger class of HIV drugs called <u>entry inhibitors</u>, which include fusion inhibitors, CCR5 antagonists, attachment inhibitors, and post-attachment inhibitors. Entry inhibitors block HIV from entering host CD4 cells.

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

- $\circ\,$ Reduce the amount of HIV in your blood. This is called viral load.
- \circ Increase the number of <u>CD4 cells</u> 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 <u>opportunistic infections (OIs)</u> that can happen when your immune system is weak. <u>Read more about viral suppression.</u>

Maraviroc <u>does not cure</u> HIV infection or <u>AIDS</u>. You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

WHO SHOULD TAKE MARAVIROC?

Maraviroc is a prescription HIV medicine used in combination with other ARVs to treat CCR5-tropic HIV infection in adults and children weighing at least 4.4 pounds (2 kg).

The safety and effectiveness of maraviroc has not been established in children weighing less than 4.4 pounds (2 kg). Maraviroc 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. <u>Read more about U.S. ART guidelines.</u>

WHO SHOULD NOT TAKE MARAVIROC?

Do not take maraviroc if you are allergic to maraviroc or any of the ingredients in this drug.

Use of maraviroc is not recommended in people with dual/mixed- or CXCR4-tropic HIV.

Do not take maraviroc if you have severe kidney problems or if you are on hemodialysis and take certain other medications.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING MARAVIROC?

Before you take maraviroc tell your healthcare provider about all of your medical conditions, and in particular if you:

- $\circ\,$ have or have had liver problems including hepatitis B virus (HBV) or hepatitis C virus (HCV) infection
- have <u>heart problems</u>
- have kidney problems
- $\circ~$ have low blood pressure or take medicines to lower blood pressure

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 maraviroc. It is not known if maraviroc will harm your unborn baby. 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 maraviroc. It is not known if maraviroc 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. <u>Read more about HIV drug resistance</u>.

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 MARAVIROC TAKEN?

Maraviroc is taken by mouth as a tablet or oral solution. The recommended dosage of maraviroc for adults depends upon what other medications are taken. The dosages are:

- $\circ~$ 300 mg daily, taken as 150 mg twice daily
- 600 mg daily, taken as 300 mg twice daily
- 1,200 mg daily, taken as 600 mg twice daily

The standard dose is 600 mg daily taken as 300 mg twice daily, in combination with other ARVs. Your healthcare provider will decide which dosage regimen is best for you based on your medical conditions and the other medicines you take.

The recommended dosage of maraviroc for children varies based on the child's weight, age, and other medicines they are taking. Your healthcare provider will determine the correct dosage.

Take maraviroc at the same time each day with or without food.

WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary <u>side effects</u> 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 maraviroc in adults are colds and cold-like symptoms, cough, fever, rash, bloating and gas, indigestion, constipation, and dizziness. The most common side effects of maraviroc in children include vomiting, abdominal pain, diarrhea, nausea, and dizziness. The most common side effect of maraviroc in newborns is decreased hemoglobin (protein inside red blood cells).

Maraviroc can cause serious side effects including:

Serious liver problems (liver toxicity). Some people who take maraviroc can develop a severe rash or an allergic reaction before liver problems happen and may be life-threatening. Stop taking maraviroc and call your healthcare provider right away if you get any of the following signs or symptoms of liver problems:

- An itchy rash on your body (allergic reaction)
- Your skin or the white part of your eyes turns yellow (jaundice)
- Dark or "tea-colored" urine
- Pale colored stools (bowel movements)
- Nausea or vomiting
- $\circ~$ Pain, aching, or tenderness on the right side of your stomach area

Your healthcare provider will do <u>blood tests</u> to check your liver before you begin treatment with maraviroc and as needed during treatment with maraviroc.

Severe skin rash and allergic reactions. Severe and potentially life-threatening skin reactions and allergic reactions have been reported in some people taking maraviroc. If you develop a rash with any of the following

symptoms, stop using maraviroc and contact your healthcare provider right away:

- Fever
- Generally ill feeling
- $\circ \ \ \text{Muscle aches}$
- Blisters or sores in your mouth
- $\circ\,$ Blisters or peeling of the skin
- Redness or swelling of the eyes
- $\circ\,$ Swelling of the mouth, face, or lips
- Problems breathing
- $\circ\,$ Yellowing of the skin or whites of your eyes
- Dark or tea-colored urine
- $\circ~$ Pain, aching, or tenderness on the right side below the ribs
- Loss of appetite
- Nausea/vomiting

Heart problems, including heart attack.

Low blood pressure when standing up (postural hypotension). Low blood pressure can cause dizziness or fainting. You should avoid driving or operating heavy machinery if you have dizziness during treatment with maraviroc.

Immune Reconstitution Inflammatory Syndrome (IRIS). <u>IRIS</u> 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 maraviroc.

Possible chance of infection or cancer. Maraviroc affects other immune system cells and therefore may possibly increase your chance for getting other infections or <u>cancer</u>.

These are not all the possible side effects of maraviroc. 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 MARAVIROC REACT WITH OTHER DRUGS?

All ARVs can <u>interact</u> 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 maraviroc with other medicines.

MORE INFORMATION

Download the full Prescribing Information

Download the Medication Guide

Check out the ViiV Healthcare Patient Assistance Program

Get a ViiV Healthcare Savings Card

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