

MEDICATION GUIDE

SELZENTRY[®] (sell-ZEN-tree) Tablets (maraviroc)

Read the Medication Guide that comes with SELZENTRY before you start taking it and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment.

What is the most important information I should know about SELZENTRY?

Liver problems

Liver problems (liver toxicity) have happened in patients taking SELZENTRY. An allergic reaction may happen before liver problems occur. Stop taking SELZENTRY and call your doctor right away if you get any of the following symptoms:

- an itchy rash on your body (allergic reaction)
- your skin or eyes look yellow and/or dark (tea-colored) urine
- vomiting and/or upper right stomach area (abdominal) pain

You should see your doctor right away but continue taking SELZENTRY if you have any of the following other symptoms: nausea, fever, flu-like symptoms, fatigue.

What is SELZENTRY?

SELZENTRY is an anti-HIV medicine called a CCR5 antagonist. HIV (Human Immunodeficiency Virus) is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

In a study of patients taking HIV medicines for the first time, the number of patients who achieved treatment success was similar in those taking either SELZENTRY or efavirenz with zidovudine and lamivudine (Combivir[®]). Nevertheless, in the same study, patients taking SELZENTRY along with zidovudine and lamivudine (Combivir[®]) failed treatment (had virus detected in their blood) and developed resistance to zidovudine (Retrovir[®]) or lamivudine (Epivir[®]) more often than patients taking efavirenz (Sustiva[®]) in combination with zidovudine and lamivudine (Combivir[®]).

SELZENTRY is used with other anti-HIV medicines in adults with CCR5-tropic HIV-1 infection. Use of SELZENTRY is not recommended in patients with dual/mixed or CXCR4-tropic HIV-1.

- SELZENTRY will not cure HIV infection.
- People taking SELZENTRY may still develop infections, including opportunistic infections or other conditions that happen with HIV infection.
- It is very important that you stay under the care of your doctor during treatment with SELZENTRY.
- The long-term effects of SELZENTRY are not known at this time.
- SELZENTRY has not been studied in children less than 16 years of age.

Does SELZENTRY lower the risk of passing HIV to other people?

No, SELZENTRY does not lower the risk of passing HIV to other people through sexual contact, sharing needles, or being exposed to your blood.

- Continue to practice safer sex.
- Use latex or polyurethane condoms or other barrier methods to lower the chance of sexual contact with any body fluids. This includes semen from a man, vaginal secretions from a woman, or blood.
- Never re-use or share needles.
- Ask your doctor if you have any questions about safer sex or how to prevent passing HIV to other people.

How does SELZENTRY work?

HIV enters cells in your blood by attaching itself to structures on the surface of the cell called receptors. SELZENTRY blocks a specific receptor called CCR5 that CCR5-tropic HIV-1 uses to enter CD4 or T-cells in your blood. Your doctor will do a blood test to see if you have been infected with CCR5-tropic HIV-1 before prescribing SELZENTRY for you.

- When used with other anti-HIV medicines, SELZENTRY may:
 - reduce the amount of HIV in your blood. This is called “viral load”.
 - increase the number of white blood cells called T (CD4) cells.

SELZENTRY does not work in all patients with CCR5-tropic HIV-1 infection.

What should I tell my doctor before taking SELZENTRY?

Tell your doctor about all of your medical conditions, including if you:

- have any allergies.
- have liver problems including a history of hepatitis B or C.
- have heart problems.
- have kidney problems.
- have low blood pressure or take medicines to lower blood pressure.
- are pregnant or planning to become pregnant. It is not known if SELZENTRY may harm your unborn baby. If you take SELZENTRY while you are pregnant, talk to your doctor about how you can be included in the Antiretroviral Pregnancy Registry.
- are breastfeeding or planning to breastfeed. It is recommended that HIV-positive women should not breastfeed their babies. This is because of the chance of passing HIV to your baby. You should not breastfeed if you are taking SELZENTRY because the risk to your baby is unknown. Talk with your doctor about the best way to feed your baby.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Certain other medicines may affect the levels of SELZENTRY in your blood. Your doctor may need to change your dose of SELZENTRY when you take it with certain medicines.

The levels of SELZENTRY in your blood may be changed and your healthcare provider may need to adjust your dose of SELZENTRY when taking any of the following medications together with SELZENTRY:

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| - darunavir (Prezista®)/ritonavir (Norvir®) | - delavirdine (Rescriptor®) |
| - lopinavir/ritonavir (Kaletra®) | - ketoconazole (Nizoral®) |
| - atazanavir (Reyataz®) ± ritonavir | - itraconazole (Sporanox®) |

- saquinavir (Invirase®) ± ritonavir
- nelfinavir (Viracept®)
- indinavir (Crixivan®)
- fosamprenavir (Lexiva®)/ritonavir
- etravirine (Intelence®)
- carbamazepine (Tegretol®)
- phenytoin (Dilantin®)

- clarithromycin (Biaxin®)
- nefazodone (Serzone®)
- telithromycin (Ketek®)
- efavirenz (Sustiva®)
- rifampin (Rifadin®)
- phenobarbital (Luminal®)

Do not take products that contain St. John's Wort (hypericum perforatum). St. John's Wort may lower the levels of SELZENTRY in your blood so that it will not work to treat your CCR5-tropic HIV infection.

Know the medicines you take. Keep a list of your medicines. Show the list to your doctor and pharmacist when you get a new medicine.

How should I take SELZENTRY?

Take SELZENTRY exactly as prescribed by your doctor. SELZENTRY comes in 150 mg and 300 mg tablets. Your doctor will prescribe the dose that is right for you.

- Take SELZENTRY twice a day.
- Swallow SELZENTRY tablets whole. Do not chew the tablets.
- Take SELZENTRY tablets with or without food.
- Always take SELZENTRY with the other anti-HIV drugs prescribed by your doctor.

Do not change your dose or stop taking SELZENTRY or your other anti-HIV medicines without first talking with your doctor.

- If you take too much SELZENTRY, call your doctor or the poison control center right away.
- If you forget to take SELZENTRY, take the next dose of SELZENTRY as soon as possible and then take your next scheduled dose at its regular time. If it is less than 6 hours before your next dose, do not take the missed dose. Wait and take the next dose at the regular time. Do not take a double dose to make up for a missed dose.
- It is very important to take all your anti-HIV medicines as prescribed and at the same time each day. This can help your medicines work better. It also lowers the chance that your medicines will stop working to fight HIV (drug resistance).
- When your SELZENTRY supply starts to run low, ask your doctor or pharmacist for a refill. This is very important because the amount of virus in your blood may increase and SELZENTRY could stop working if it is stopped for even a short period of time.

What are the possible side effects of SELZENTRY?

When SELZENTRY has been given with other anti-HIV drugs, there have been serious side effects including:

- **Liver problems.** See “What is the most important information I should know about SELZENTRY?”
- **Heart problems** including heart attack.

- **Low blood pressure when standing up (postural hypotension).** Low blood pressure when standing up can cause dizziness or fainting. Do not drive a car or operate heavy machinery if you have dizziness while taking SELZENTRY.
- **Changes in your immune system.** A condition called Immune Reconstitution Syndrome can happen when you start taking HIV medicines. Your immune system may get stronger and could begin to fight infections that have been hidden in your body such as pneumonia, herpes virus or tuberculosis. Tell your doctor if you develop new symptoms after starting your HIV medicines.
- **Possible chance of infection or cancer.** SELZENTRY affects other immune system cells and therefore may possibly increase your chance for getting other infections or cancer, although there is no evidence from the clinical trials of an increase in serious infections or cancer.

The most common side effects of SELZENTRY include colds, cough, fever, rash, gastrointestinal side effects including gas and bloating, and dizziness. Tell your doctor about any side effect that bothers you or does not go away.

These are not all of the side effects with SELZENTRY. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store SELZENTRY?

- Store SELZENTRY tablets at room temperature from 59°F to 86°F (15°C to 30°C).
- Safely throw away medicine that is out of date or that you no longer need.
- **Keep SELZENTRY and all medicines out of the reach of children.**

General information about SELZENTRY

Medicines are sometimes prescribed for conditions that are not mentioned in Medication Guides. Do not use SELZENTRY for a condition for which it was not prescribed. Do not give SELZENTRY to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about SELZENTRY. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for more information about SELZENTRY that is written for health professionals. For more information go to www.selzentry.com.

What are the ingredients in SELZENTRY?

Active Ingredient: maraviroc

Inactive Ingredients:

Tablet core: microcrystalline cellulose, dibasic calcium phosphate (anhydrous), sodium starch glycolate, magnesium stearate

Film-coat: FD&C blue #2 aluminum lake, soya lecithin, polyethylene glycol (macrogol 3350), polyvinyl alcohol, talc and titanium dioxide

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