

# KEY POINTS TO REMEMBER

## ABOUT SELZENTRY® (maraviroc)

### APPROVED USE

SELZENTRY is a prescription HIV-1 (Human Immunodeficiency Virus type 1) medicine used with other antiretroviral medicines to treat CCR5-tropic HIV-1 infection in people 2 years of age and older weighing at least 22 lb (10 kg). HIV-1 is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). Use of SELZENTRY is not recommended in people with dual/mixed or CXCR4-tropic HIV-1. The safety and effectiveness of SELZENTRY has not been established in children younger than 2 years of age. SELZENTRY comes in 25-mg, 75-mg, 150-mg, and 300-mg tablets, and a 20-mg/mL oral solution.

### CCR5-tropic HIV-1

- A tropism test can help your healthcare provider determine whether your virus is CCR5 tropic
- CCR5-tropic HIV-1 is more common during the early stages of HIV-1 infection and in those who have not been treated for HIV-1 infection before. However, no matter where you are in your treatment journey, your doctor may perform a tropism test to see if SELZENTRY may be right for you
- SELZENTRY helps inhibit the entry of CCR5-tropic HIV-1 into white blood cells called CD4<sup>+</sup> T-cells

### SELZENTRY helps block entry of HIV-1

- By working on the outer surface of the CD4<sup>+</sup> T-cells, SELZENTRY helps prevent the attachment of CCR5-tropic HIV-1 to the CCR5 coreceptor on the CD4<sup>+</sup> T-cells
- When used with other HIV-1 medicines, SELZENTRY may reduce the amount of HIV-1 in your blood (viral load) and may increase the number of CD4<sup>+</sup> T-cells

Ask your healthcare provider if SELZENTRY is right for you.

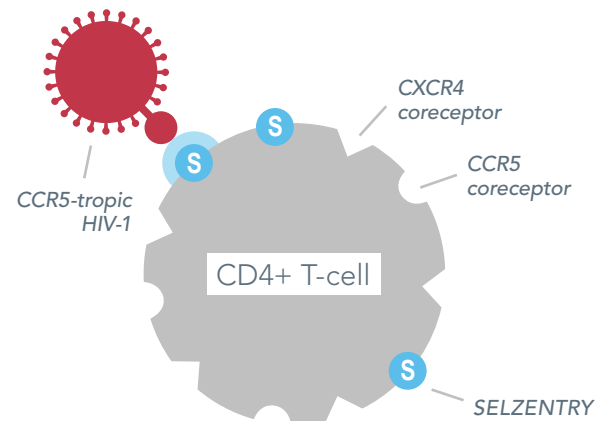


Illustration only. Not actual representation of HIV.

### IMPORTANT SAFETY INFORMATION

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

**SELZENTRY can cause serious side effects including serious liver problems (liver toxicity).** An allergic reaction may happen before liver problems occur. **Stop taking SELZENTRY 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
- vomiting
- pain, aching, or tenderness on the right side of your stomach area

Your healthcare provider will do blood tests to check your liver before you begin treatment with SELZENTRY and as needed during treatment, and if you get a severe rash, signs and symptoms of liver problems, or an allergic reaction during treatment with SELZENTRY.

#### Who should not take SELZENTRY?

**Do not take SELZENTRY if you** have severe kidney problems or are on hemodialysis and are also taking certain other medications.

**Please see additional Important Safety Information for SELZENTRY on pages 2-3.**

**Please see full Prescribing Information, including Boxed Warning and Medication Guide, available at [selzentry.com](http://selzentry.com)**

## IMPORTANT SAFETY INFORMATION (cont'd)



### What should I tell my healthcare provider before taking SELZENTRY?

#### Before you take SELZENTRY, tell your healthcare provider if you:

- have or have had liver problems including hepatitis B or C virus infection.
- have heart problems.
- have kidney problems.
- have low blood pressure or take medicines to lower blood pressure.
- are pregnant or plan to become pregnant. It is not known if SELZENTRY may harm your unborn baby.
- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take SELZENTRY.** You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some medicines may interact with SELZENTRY. **Keep a list of your medicines to show your healthcare provider and pharmacist.** You can ask your healthcare provider or pharmacist for a list of medicines that interact with SELZENTRY. **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take SELZENTRY with other medicines.

Your healthcare provider may need to change your dose of SELZENTRY when you take it with certain medicines.

**You should not take SELZENTRY if you also take St. John's wort.**

### What are the possible side effects of SELZENTRY?

- **SELZENTRY can cause serious side effects including:**
- **See "What is the most important information I should know about SELZENTRY?"**
- **Serious skin rash and allergic reactions.** Severe and potentially life-threatening skin reactions and allergic reactions have been reported in some patients taking SELZENTRY. If you develop a rash with any of the following symptoms, stop using SELZENTRY and contact your doctor right away:
  - fever
  - generally ill feeling
  - muscle aches
  - blisters or sores in your mouth
  - blisters or peeling of the skin
  - redness or swelling of the eyes
  - swelling of the mouth or face or lips
  - problems breathing
  - yellowing of the skin or whites of your eyes
  - dark or tea-colored urine
  - 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)** can cause dizziness or fainting. You should avoid driving or operating heavy machinery if you have dizziness while taking SELZENTRY.
- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV-1 medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. Tell your healthcare provider right away if you develop new symptoms after you start taking SELZENTRY.
- **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.

**Please see additional Important Safety Information for SELZENTRY on page 3.**

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## **IMPORTANT SAFETY INFORMATION (cont'd)**

**The most common side effects of SELZENTRY in adults include** colds and cold-like symptoms, cough, fever, rash, bloating and gas, indigestion, constipation, and dizziness.



**The most common side effects of SELZENTRY in children include** vomiting, abdominal pain, diarrhea, nausea, and dizziness.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

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

Take SELZENTRY 2 times a day. Swallow tablets whole. Do not chew the tablets. You can take SELZENTRY tablets with or without food.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

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