

769 consulting their physician. If a dose is missed, patients should take the next dose of
770 SELZENTRY as soon as possible and then take their next scheduled dose at its regular time. If it
771 is less than 6 hours before their next scheduled dose, they should not take the missed dose and
772 should instead wait and take the next dose at the regular time.

773 Patients should be advised that when their supply of SELZENTRY starts to run low, they
774 should ask their doctor or pharmacist for a refill.

775

776 Caution should be used when administering SELZENTRY in patients with a history of
777 postural hypotension or on concomitant medication known to lower blood pressure. Patients
778 should be advised that if they experience dizziness while taking SELZENTRY, they should
779 avoid driving or operating machinery.

780

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782

783 Manufactured for:



784

785 ViiV Healthcare

786 Research Triangle Park, NC 27709

787

788 by:

789 Pfizer Manufacturing Deutschland GmbH

790 Freiburg, Germany

791

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793

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795 SEL: XPI

796

797 PHARMACIST-DETACH HERE AND GIVE MEDICATION GUIDE TO PATIENT

798

799

MEDICATION GUIDE

800

SELZENTRY[®] (sell-ZEN-tree) Tablets

801

(maraviroc)

802

803 Read the Medication Guide that comes with SELZENTRY before you start taking it

804 and each time you get a refill. There may be new information. This information

805 does not take the place of talking with your healthcare provider about your medical
806 condition or treatment.

807

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

809

810 **Serious side effects have occurred with SELZENTRY, including liver**
811 **problems (liver toxicity).** An allergic reaction may happen before liver problems
812 occur. Stop taking SELZENTRY and call your healthcare provider right away if you
813 get any of the following symptoms:

- 814 • an itchy rash on your body (allergic reaction)
- 815 • yellowing of your skin or whites of your eyes (jaundice)
- 816 • dark (tea-colored) urine
- 817 • vomiting
- 818 • upper right stomach area (abdominal) pain

819

820 **What is SELZENTRY?**

821 SELZENTRY is an anti-HIV medicine called a CCR5 antagonist. HIV-1 (Human
822 Immunodeficiency Virus) is the virus that causes AIDS (Acquired Immune
823 Deficiency Syndrome).

824

825 SELZENTRY is used with other anti-HIV medicines in adults with CCR5-tropic HIV-1
826 infection.

827

828 Use of SELZENTRY is not recommended in people with dual/mixed or CXCR4-tropic
829 HIV-1.

830

- 831 • SELZENTRY will not cure HIV-1 infection.
- 832 • People taking SELZENTRY may still develop infections, including opportunistic
833 infections or other conditions that happen with HIV-1 infection.
- 834 • It is very important that you stay under the care of your healthcare provider
835 during treatment with SELZENTRY.
- 836 • The long-term effects of SELZENTRY are not known at this time.

837

838 SELZENTRY has not been studied in children less than 16 years of age.

839

840 **General information about SELZENTRY**

841 SELZENTRY does not cure HIV-1 infection and you may continue to experience
842 illnesses associated with HIV-1 infection, including opportunistic infections. You
843 should remain under the care of a doctor when using SELZENTRY.

844

- 845 Avoid doing things that can spread HIV-1 infection.
- 846 • **Do not share needles or other injection equipment.**
 - 847 • **Do not share personal items that can have blood or body fluids on them,**
 - 848 **like toothbrushes and razor blades.**
 - 849 • **Do not have any kind of sex without protection.** Always practice safe sex
 - 850 by using a latex or polyurethane condom to lower the chance of sexual contact
 - 851 with semen, vaginal secretions, or blood.

852
853

854 **How does SELZENTRY work?**

855 HIV-1 enters cells in your blood by attaching itself to structures on the surface of

856 the cell called receptors. SELZENTRY blocks a specific receptor called CCR5 that

857 CCR5-tropic HIV-1 uses to enter CD4 or T-cells in your blood. Your healthcare

858 provider will do a blood test to see if you have been infected with CCR5-tropic

859 HIV-1 before prescribing SELZENTRY for you.

860

- 861 • When used with other anti-HIV medicines, SELZENTRY may:
 - 862 • reduce the amount of HIV-1 in your blood. This is called “viral load”.
 - 863 • increase the number of white blood cells called T (CD4) cells.

864

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

866

867 **Who should not take SELZENTRY?**

868 People with severe kidney problems or who are on hemodialysis and are taking

869 certain other medications should not take SELZENTRY. Talk to your healthcare

870 provider before taking this medicine if you have kidney problems.

871

872 **What should I tell my healthcare provider before taking SELZENTRY?**

873

874 **Before you take SELZENTRY, tell your healthcare provider if you:**

- 875 • have liver problems including a history of hepatitis B or C.
- 876 • have heart problems.
- 877 • have kidney problems.
- 878 • have low blood pressure or take medicines to lower blood pressure.
- 879 • have any other medical condition.
- 880 • are pregnant or plan to become pregnant. It is not known if SELZENTRY may
- 881 harm your unborn baby.

882 **Antiretroviral Pregnancy Registry.** There is a pregnancy registry for women

883 who take antiviral medicines during pregnancy. The purpose of the registry is to

884 collect information about the health of you and your baby. Talk to your
885 healthcare provider about how you can take part in this registry.
886 • are breastfeeding or plan to breastfeed. **Do not breastfeed.** We do not know if
887 SELZENTRY can be passed to your baby in your breast milk and whether it could
888 harm your baby. Also, mothers with HIV-1 should not breastfeed because HIV-1
889 can be passed to the baby in the breast milk. Talk with your healthcare provider
890 about the best way to feed your baby.

891
892 **Tell your healthcare provider about all the medicines you take**, including
893 prescription and non-prescription medicines, vitamins, and herbal supplements.
894 Certain other medicines may affect the levels of SELZENTRY in your blood. Your
895 healthcare provider may need to change your dose of SELZENTRY when you take it
896 with certain medicines.

897
898 The levels of SELZENTRY in your blood may change and your healthcare provider
899 may need to adjust your dose of SELZENTRY when taking any of the following
900 medications together with SELZENTRY:

- 901
- | | |
|---|--|
| 902 - darunavir (Prezista [®]) | - delavirdine (Rescriptor [®]) |
| 903 - lopinavir/ritonavir (Kaletra [®] , Norvir [®]) | - ketoconazole (Nizoral [®]) |
| 904 - atazanavir (Reyataz [®]) | - itraconazole (Sporanox [®]) |
| 905 - saquinavir (Invirase [®]) | - clarithromycin (Biaxin [®]) |
| 906 - nelfinavir (Viracept [®]) | - nefazodone (Serzone [®]) |
| 907 - indinavir (Crixivan [®]) | - telithromycin (Ketek [®]) |
| 908 - fosamprenavir (Lexiva [®]) | - efavirenz (Sustiva [®] , Atripla [®]) |
| 909 - etravirine (Intelence [®]) | - rifampin (Rifadin [®] , Rifater [®]) |
| 910 - carbamezepine (Tegretol [®]) | - phenobarbital (Luminal [®]) |
| 911 - phenytoin (Dilantin [®]) | |
| 912 - Ritonavir (Norvir [®]) | |

913
914 **Do not take products that contain St. John's Wort (*hypericum perforatum*).**
915 **St. John's Wort may lower the levels of SELZENTRY in your blood so that it**
916 **will not work to treat your CCR5-tropic HIV infection.**

917 **Know the medicines you take.** Keep a list of your medicines. Show the list to
918 your healthcare provider and pharmacist when you get a new medicine.

919
920 **How should I take SELZENTRY?**

921

922 **Take SELZENTRY exactly as prescribed by your healthcare provider.**
923 SELZENTRY comes in 150-mg and 300-mg tablets. Your healthcare provider will
924 prescribe the dose that is right for you.

- 925 • Take SELZENTRY 2 times a day.
- 926 • Swallow SELZENTRY tablets whole. Do not chew the tablets.
- 927 • Take SELZENTRY tablets with or without food.
- 928 • Always take SELZENTRY with other anti-HIV drugs as prescribed by your
929 healthcare provider.

930

931 **Do not change your dose or stop taking SELZENTRY or your other anti-HIV**
932 **medicines without first talking with your healthcare provider.**

933

- 934 • If you take too much SELZENTRY, call your healthcare provider or the poison
935 control center right away.
- 936 • If you forget to take SELZENTRY, take the next dose of SELZENTRY as soon as
937 possible and then take your next scheduled dose at its regular time. If it is less
938 than 6 hours before your next dose, do not take the missed dose. Wait and take
939 the next dose at the regular time. Do not take a double dose to make up for a
940 missed dose.
- 941 • It is very important to take all your anti-HIV medicines as prescribed. This can
942 help your medicines work better. It also lowers the chance that your medicines
943 will stop working to fight HIV-1 (drug resistance).
- 944 • When your SELZENTRY supply starts to run low, ask your healthcare provider or
945 pharmacist for a refill. This is very important because the amount of virus in
946 your blood may increase and SELZENTRY could stop working if it is stopped for
947 even a short period of time.

948

949 **What are the possible side effects of SELZENTRY?**

950

951 **There have been serious side effects when SELZENTRY has been given with**
952 **other anti-HIV drugs including:**

- 953 • **Liver problems.** See “What is the most important information I should know
954 about SELZENTRY?”
- 955 • **Heart problems** including heart attack.
- 956 • **Low blood pressure when standing up (postural hypotension).** Low blood
957 pressure when standing up can cause dizziness or fainting. Do not drive a car or
958 operate heavy machinery if you have dizziness while taking SELZENTRY.
- 959 • **Changes in your immune system.** A condition called Immune Reconstitution
960 Syndrome can happen when you start taking HIV medicines. Your immune
961 system may get stronger and could begin to fight infections that have been

962 hidden in your body such as pneumonia, herpes virus, or tuberculosis. Tell your
963 healthcare provider if you develop new symptoms after starting your HIV
964 medicines.

- 965 • **Possible chance of infection or cancer.** SELZENTRY affects other immune
966 system cells and therefore may possibly increase your chance for getting other
967 infections or cancer.

968

969 **The most common side effects of SELZENTRY include** colds, cough, fever,
970 rash, and dizziness.

971

972 Tell your healthcare provider about any side effect that bothers you or does not go
973 away.

974

975 These are not all of the side effects with SELZENTRY. For more information, ask
976 your healthcare provider or pharmacist.

977

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

980

981 **How should I store SELZENTRY?**

- 982 • Store SELZENTRY tablets at room temperature from 59°F to 86°F (15°C to
983 30°C).
- 984 • Safely throw away medicine that is out of date or that you no longer need.

985

986 **Keep SELZENTRY and all medicines out of the reach of children.**

987

988 **General information about SELZENTRY**

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

993

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

999

1000 **What are the ingredients in SELZENTRY?**

1001 **Active ingredient:** maraviroc

1002 **Inactive ingredients:** microcrystalline cellulose, dibasic calcium phosphate
1003 (anhydrous), sodium starch glycolate, magnesium stearate
1004 **Film-coat:** FD&C blue #2 aluminum lake, soya lecithin, polyethylene glycol
1005 (macrogol 3350), polyvinyl alcohol, talc, and titanium dioxide
1006

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1009 affiliated with and do not endorse ViiV Healthcare or its products.
1010

1011 This Medication Guide has been approved by the US Food and Drug Administration.
1012
1013

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