Table 6: Effect of Co-administered Agents on the Pharmacokinetics of Maraviroc

Co-administered drug and dose	N	Maraviroc Dose	Ratio (90% CI) of maraviroc pharmacokinetic parameters with/without co-administered drug (no effect = 1.00)		
			Cmin	**AUC_{tau}**	**Cmax**
CYP3A and/or P-gp Inhibitors					
Ketoconazole 400 mg QD	12	100 mg BID	3.75 (3.01-4.69)	5.00 (3.98, 6.29)	3.38 (2.38, 4.78)
Ritonavir 100 mg BID	8	100 mg BID	4.55 (3.37-6.13)	2.61 (1.92, 3.56)	1.28 (0.79, 2.09)
Saquinavir (soft gel capsules) /ritonavir 1000 mg/100 mg BID	11	100 mg BID	11.3 (8.96-14.1)	9.77 (7.87, 12.14)	4.78 (3.41, 6.71)
Lopinavir/ritonavir 400 mg/100 mg BID	11	300 mg BID	9.24 (7.98-10.7)	3.95 (3.43, 4.56)	1.97 (1.66, 2.34)
Atazanavir 400 mg QD	12	300 mg BID	4.19 (3.65-4.80)	3.57 (3.30, 3.87)	2.09 (1.72, 2.55)
Atazanavir/ritonavir 300 mg/100 mg QD	12	300 mg BID	6.67 (5.78-7.70)	4.88 (4.40, 5.41)	2.67 (2.32, 3.08)
CYP3A and/or P-gp Inducers					
Efavirenz 600 mg QD	12	100 mg BID	0.55 (0.43-0.72)	0.552 (0.492, 0.620)	0.486 (0.377, 0.626)
Rifampicin 600 mg QD	12	100 mg BID	0.22 (0.17-0.28)	0.368 (0.328, 0.413)	0.335 (0.260, 0.431)
Nevirapine* 200 mg BID (+ lamivudine 150 mg BID, tenofovir 300 mg QD)	8	300 mg SD	-	1.01 (0.65, 1.55)	1.54 (0.94, 2.51)
CYP3A and/or P-gp Inhibitors and Inducers					
Lopinavir/ritonavir + efavirenz 400 mg/100 mg BID + 600 mg QD	11	300 mg BID	6.29 (4.72-8.39)	2.53 (2.24, 2.87)	1.25 (1.01, 1.55)
Saquinavir(soft gel capsules) /ritonavir + efavirenz 1000 mg/100 mg BID + 600 mg QD	11	100 mg BID	8.42 (6.46-10.97)	5.00 (4.26, 5.87)	2.26 (1.64, 3.11)
Tipranavir/ritonavir 500 mg/200 mg BID	12	150 mg BID	1.80 (1.55-2.09)	1.02 (0.850, 1.23)	0.86 (0.61, 1.21)

*** Compared to historical data**

Effect of Maraviroc on the Pharmacokinetics of Concomitant Drugs

Maraviroc is unlikely to inhibit the metabolism of co-administered drugs metabolized by the following cytochrome P enzymes (CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19, and CYP3A) because maraviroc did not inhibit activity of those enzymes at clinically relevant concentrations in vitro.

Drug interaction studies were performed with maraviroc and other drugs likely to be co-administered or commonly used as probes for pharmacokinetic interactions [see Table 6]. Maraviroc had no effect on the pharmacokinetics of zidovudine or lamivudine. Maraviroc had no clinically relevant effect on the pharmacokinetics of midazolam, the oral contraceptives ethinylestradiol and levonorgestrel, no effect on the urinary 6β-hydroxycortisol/cortisol ratio, suggesting no induction of CYP3A in vivo. Maraviroc had no effect on the debrisoquine metabolic ratio (MR) at 300 mg twice daily or less in vivo. However, there was 234% increase in debrisoquine MR on treatment compared to baseline at 600 mg once daily, suggesting potential inhibition of CYP2D6 at higher dose.

12.4 MICROBIOLOGY

Mechanism of Action

Maraviroc is a member of a therapeutic class called CCR5 co-receptor antagonists. Maraviroc selectively binds to the human chemokine receptor CCR5 present on the cell membrane, preventing the interaction of HIV-1 gp120 and CCR5 necessary for CCR5-tropic HIV-1 to enter cells. CXCR4-tropic and dual-tropic HIV-1 entry is not inhibited by maraviroc.

Antiviral Activity in Cell Culture

Maraviroc inhibits the replication of CCR5-tropic laboratory strains and primary isolates of HIV-1 in models of acute T-cell infection. The mean EC_{50} value (50% effective concentration) for maraviroc against HIV-1 group M isolates (clades A to J) and group O isolates ranged from 0.1 to 1.25 nM (0.05 to 0.64 ng/mL) in cell culture.

When used with other antiretroviral agents in cell culture, the combination of maraviroc was not antagonistic with NNRTIs (delavirdine, efavirenz and nevirapine), NRTIs (abacavir, didanosine, emtricitabine, lamivudine, stavudine, tenofovir, zalcitabine and zidovudine), or protease inhibitors (amprenavir, atazanavir, indinavir, lopinavir, nelfinavir, ritonavir and saquinavir). Maraviroc was additive/synergistic with the HIV fusion inhibitor enfuvirtide. Maraviroc was not active against CXCR4-tropic and dual-tropic viruses (EC_{50} value >10 μM). The antiviral activity of maraviroc against HIV-2 has not been evaluated.

Resistance in Cell Culture

HIV-1 variants with reduced susceptibility to maraviroc have been selected in cell culture, following serial passage of two CCR5-tropic viruses (CC1/85 and RU570). The maraviroc-resistant viruses remained CCR5-tropic with no evidence of a change from a CCR5-tropic virus to a CXCR4-using virus. Two amino acid residue substitutions in the V3-loop region of the HIV-1 envelope glycoprotein (gp160), A316T and I323V (HXB2 numbering) were shown to be necessary for the maraviroc-resistant phenotype in the HIV-1 isolate CC1/85. In the RU570 isolate a 3-amino acid residue deletion in the V3 loop, ΔQAI (HXB2 positions 315-317), was associated with maraviroc-resistance. The relevance of the specific gp120 mutations observed in maraviroc-resistant isolates selected in cell culture to clinical maraviroc resistance is not known. Maraviroc-resistant viruses were characterized phenotypically by concentration response curves that did not reach 100% inhibition in phenotypic drug assays, rather than increases in EC_{50} values.

Clinical Resistance

The resistance profile in treatment-naïve and treatment-experienced subjects has not been fully characterized. Virologic failure on maraviroc can result from genotypic and phenotypic resistance to maraviroc or through outgrowth of undetected CXCR4-using virus present before

maraviroc treatment (see *Tropism* below). Preliminary data from a subset of treatment-experienced subjects failing maraviroc-containing regimens with CCR5-tropic virus (n=12) have identified 5 viruses that had decreased susceptibility to maraviroc characterized in phenotypic drug assays by concentration response curves that did not reach 100% inhibition. Additionally, CCR5-tropic virus from 2 of these treatment failure subjects had 3-fold shifts in EC_{50} values for maraviroc at the time of failure.

Each of these viruses had multiple amino acid substitutions with unique patterns in the heterogeneous V3 loop region of gp120. Changes at either amino acid position 308 or 323 (HXB2 numbering) were seen in the V3 loop in all five of the subjects with decreased maraviroc susceptibility. The contribution of mutations outside the V3 loop of gp120 to maraviroc resistance has not been investigated.

Cross-resistance in Cell Culture

Maraviroc had antiviral activity against HIV-1 clinical isolates resistant to NRTIs, NNRTIs, PIs and enfuvirtide in cell culture (EC_{50} values ranged from 0.7 to 8.9 nM (0.36 to 4.57 ng/mL)). Maraviroc-resistant viruses that emerged in cell culture remained susceptible to the fusion inhibitor enfuvirtide and the protease inhibitor saquinavir.

Tropism

In the majority of cases, treatment failure on maraviroc was associated with detection of CXCR4-using (i.e., CXCR4- or dual/mixed-tropic) virus which was not detected by the tropism assay prior to treatment. CXCR4-using virus was detected at failure in approximately 60% of subjects who failed treatment on maraviroc, as compared to 6% of subjects who experienced treatment failure in the placebo arm. To investigate the likely origin of the on-treatment CXCR4-using virus, a detailed clonal analysis was conducted on virus from 20 representative subjects (16 subjects from the maraviroc arms and 4 subjects from the placebo arm) in whom CXCR4-using virus was detected at treatment failure. From analysis of amino acid sequence differences and phylogenetic data, CXCR4-using virus in these subjects emerged from a low level of pre-existing CXCR4-using virus not detected by the tropism assay (which is population-based) prior to treatment rather than from a co-receptor switch from CCR5-tropic virus to CXCR4-using virus resulting from mutation in the virus.

Detection of CXCR4-using virus prior to initiation of therapy has been associated with a reduced virological response to maraviroc. Furthermore, subjects failing maraviroc BID with CXCR4-using virus had a lower median increase in $CD4^+$ cell counts from baseline (+22 cells/mm^3) than those subjects failing with CCR5-tropic virus (+149 cells/mm^3). The median increase in $CD4^+$ cell count in patients failing in the placebo arm was +5 cells/mm^3.

12.5 Pharmacogenomics

The impact of CCR5 promoter and coding sequence polymorphisms on the efficacy of maraviroc is being evaluated.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

Long-term oral carcinogenicity studies of maraviroc were carried out in rasH2 transgenic mice (6 months) and in rats for up to 96 weeks (females) and 104 weeks (males). No drug-related

increases in tumor incidence were found in mice at 1500 mg/kg/day and in male and female rats at 900 mg/kg/day. The highest exposures in rats were approximately 11 times those observed in humans at the therapeutic dose of 300 mg twice daily for the treatment of HIV-1 infection.

Mutagenesis

Maraviroc was not genotoxic in the reverse mutation bacterial test (Ames test in Salmonella and E. coli), a chromosome aberration test in human lymphocytes and rat bone marrow micronucleus test.

Impairment of Fertility

Maraviroc did not impair mating or fertility of male or female rats and did not affect sperm of treated male rats at approximately 20-fold higher exposures (AUC) than in humans given the recommended 300 mg twice daily dose.

14 CLINICAL STUDIES

The clinical efficacy and safety of SELZENTRY is derived from analyses of 24-week data from two ongoing studies, A4001027 (MOTIVATE-1) and A4001028 (MOTIVATE-2), in antiretroviral treatment-experienced adult subjects infected with CCR5-tropic HIV-1. These studies are supported by a 24-week study in antiretroviral treatment-experienced adult subjects infected with dual/mixed-tropic HIV-1, A4001029.

14.1 Studies in CCR5-tropic, Treatment-Experienced Subjects

Studies A4001027 and A4001028 are ongoing, double-blind, randomized, placebo-controlled, multicenter studies in subjects infected with CCR5-tropic HIV-1. Subjects were required to have an HIV-1 RNA of greater than 5,000 copies/mL despite at least 6 months of prior therapy with at least one agent from three of the four antiretroviral drug classes [≥1 nucleoside reverse transcriptase inhibitors (NRTI), ≥1 non-nucleoside reverse transcriptase inhibitors (NNRTI), ≥2 protease inhibitors (PI), and/or enfuvirtide] or documented resistance or intolerance to at least one member of each class. All subjects received an optimized background regimen consisting of 3 to 6 antiretroviral agents (excluding low-dose ritonavir) selected on the basis of the subject's prior treatment history and baseline genotypic and phenotypic viral resistance measurements. In addition to the optimized background regimen, subjects were then randomized in a 2:2:1 ratio to maraviroc 300 mg once daily, maraviroc 300 mg twice daily, or placebo. Doses were adjusted based on background therapy as described in *Dosing and Administration*, Table 1.

In the pooled analysis for A4001027 and A4001028, the demographics and baseline characteristics of the treatment groups were comparable (Table 7). Of the 1043 subjects with a CCR5 tropism result at screening, 7.6% had a dual/mixed tropism result at the baseline visit 4 to 6 weeks later. This illustrates the background change from CCR5 to dual/mixed tropism result over time in this treatment-experienced population, prior to a change in antiretroviral regimen or administration of a CCR5 co-receptor antagonist.

Table 7
Demographic and Baseline Characteristics of Subjects in Studies A4001027 and A4001028

	~~SELZENTRY~~ BID N = 426	~~Placebo~~ N = 209
~~Age (years)~~ Mean (Range)	46.3 (21-73)	45.7 (29-72)
~~Sex~~ ~~Male~~	~~382 (89.7%)~~	~~185 (88.5%)~~

Female	44 (10.3%)	24 (11.5%)
Race		
White	363 (85.2%)	178 (85.2%)
Black	51 (12.0%)	26 (12.4%)
Other	12 (2.8%)	5 (2.4%)
Region		
U.S.	276 (64.8%)	135 (64.6%)
Non-U.S.	150 (35.2%)	74 (35.4%)
Subjects with Previous Enfuvirtide Use	182 (42.7%)	91 (43.5%)
Baseline Plasma HIV-1 RNA (log_{10} copies/mL)		
Mean (Range)	4.85 (2.96-6.88)	4.86 (3.46-7.07)
Subjects with Screening Viral Load >100,000 copies/mL	179 (42.0%)	84 (40.2%)
Baseline CD4+ Cell Count (cells/mm^3)		
Median (Range)	167 (2-820)	171 (1-675)
Subjects with Baseline CD4+ Cell Count ≤200 cells/mm^3)	250 (58.7%)	118 (56.7%)
Subjects with Overall Susceptibility Score (OSS):[a]		
0	57 (13.4%)	35 (16.7%)
1	136 (31.9%)	44 (21.1%)
2	104 (24.4%)	59 (28.2%)
≥3	125 (29.3%)	66 (31.6%)
Subjects with enfuvirtide resistance mutations	90 (21.2%)	45 (21.5%)
Median Number of Resistance-Associated:[b]		
PI mutations	10	10
NNRTI mutations	1	1
NRTI mutations	6	6

[a] OSS=Sum of active drugs in OBT based on combined information from genotypic and phenotypic testing.

[b] Resistance mutations based on IAS guidelines[1]

The week 24 results for the pooled Studies A4001027 and A4001028 are shown in Table 8.

Table 8
Outcomes of Randomized Treatment at Week 24
Studies A4001027 and A4001028

Outcome	SELZENTRY BID N=426	PLACEBO N=209	Mean Difference
Mean change from Baseline to Week 24 in HIV-1 RNA (log_{10} copies/mL)	-1.96	-0.99	0.97
<400 copies/mL at Week 24	259 (60.8%)	58 (27.8%)	33.0%
<50 copies/mL at Week 24	193 (45.3%)	48 (23.0%)	22.3%
Virologic Responders[b]	295 (69.2%)	75 (35.9%)	33.4%
Discontinuations			
Insufficient Clinical Response	91 (21.4%)	106 (50.7%)	
Adverse Events	16 (3.8%)	8 (3.8%)	
Other	26 (6.1%)	18 (8.6%)	
Patients with treatment-emergent CDC Category C events	18 (4.2%)	14 (6.7%)	
Deaths (during study or within 28 days of last dose)	5 (1.2%)	1 (0.5%)	

[b] Reduction in HIV-1 RNA ≥1 log_{10} or HIV-1 RNA <400 copies/mL at Week 24.

After 24 weeks of therapy, the proportion of subjects with HIV-1 RNA <400 copies/mL receiving maraviroc compared to placebo was 61% and 28%, respectively. The mean changes in plasma HIV-1 RNA from baseline to week 24 was –1.96 log_{10} copies/mL for subjects receiving

maraviroc + OBT compared to –0.99 $\log_{10}$ copies/mL for subjects receiving OBT only. The mean increase in CD4+ counts was higher on maraviroc twice daily + OBT (106.3 cells/mm^3) than on placebo + OBT (57.4 cells/mm^3).

14.2 Study in Dual/Mixed-tropic, Treatment-Experienced Subjects

Study A4001029 was an exploratory, randomized, double blind, multicenter trial to determine the safety and efficacy of maraviroc in subjects infected with dual/mixed co-receptor tropic HIV-1. The inclusion/exclusion criteria were similar to those for Studies A4001027 and A4001028 above and the subjects were randomized in a 1:1:1 ratio to SELZENTRY once daily, SELZENTRY twice daily, or placebo. No increased risk of infection or HIV disease progression was observed in the subjects who received SELZENTRY. SELZENTRY use was not associated with a significant decrease in HIV-1 RNA compared to placebo in these subjects and no adverse effect on CD4 count was noted.

15 REFERENCES

[1]IAS-USA Drug Resistance Mutations Figures
http://www.iasusa.org/pub/topics/2006/issue3/125.pdf

16 HOW SUPPLIED/STORAGE AND HANDLING

SELZENTRY film-coated tablets are available as follows:

150 and 300 mg tablets are blue, biconvex, oval film-coated tablets debossed with "Pfizer" on one side and "MVC 150" or "MVC 300" on the other.

Bottle packs 150 mg tablets

- 60 tablets (NDC 0069-0807-60)

Bottle packs 300 mg tablets

- 60 tablets (NDC 0069-0808-60)

SELZENTRY film-coated tablets should be stored at 25°C (77°F); excursions permitted between 15° and 30°C (59°-86°F) [see USP Controlled Room Temperature].

Shelf life is 24 months.

17 PATIENT COUNSELING INFORMATION

See Medication Guide.

Patients should be informed that if they develop signs or symptoms of hepatitis or allergic reaction following use of SELZENTRY (rash, skin or eyes look yellow, dark urine, vomiting, abdominal pain), they should stop SELZENTRY and seek medical evaluation immediately [*see Warnings and Precautions (5.1)*].

Patients should be informed that SELZENTRY is not a cure for HIV infection and patients may still develop illnesses associated with HIV infection, including opportunistic infections. The use of SELZENTRY has not been shown to reduce the risk of transmission of HIV to others through sexual contact, sharing needles or blood contamination.

Patients should be advised that it is important to:

- remain under the care of a physician when using SELZENTRY;
- take SELZENTRY every day as prescribed and in combination with other antiretroviral drugs;
- report to their physician the use of any other prescription or nonprescription medication or herbal products;
- inform their physician if they are pregnant, plan to become pregnant or become pregnant while taking SELZENTRY;
- not change the dose or dosing schedule of SELZENTRY or any antiretroviral medication without consulting their physician.

Patients should be advised that if they forget to take a dose, they should take the next dose of SELZENTRY as soon as possible and then take their next scheduled dose at its regular time. If it is less than 6 hours before their next scheduled dose, they should not take the missed dose and should instead wait and take the next dose at the regular time.

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

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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).

SELZENTRY is used with other anti-HIV medicines in adults with CCR5-tropic HIV-1 infection who are already taking anti-HIV medicines and the medicines are not controlling their HIV infection.

- 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.

  Both of these may keep your immune system healthy, so it can help fight infection.

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 breast-feeding or planning to breast-feed. It is recommended that HIV-positive women should not breastfeed their babies. This is because of the chance of passing HIV to your baby. 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.

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 cough, fever, colds, rash, muscle and joint pain, stomach pain, 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.

How should I store SELZENTRY?

- Store SELZENTRY tablets at room temperature from 59°F to 86° (15°Cto 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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