

VIRACEPT

nelfinavir mesylate
tablets and oral powder

Information for Patients About VIRACEPT® (Vi-ra-cept)
Generic Name: nelfinavir (nel-FIN-na-veer) mesylate

For the Treatment of Human Immunodeficiency Virus (HIV) Infection
Please read this information carefully before taking VIRACEPT. Also, please read this leaflet each time you renew the prescription, just in case anything has changed. This is a summary and not a replacement for a careful discussion with your doctor. You and your doctor should discuss VIRACEPT when you start taking this medication and at regular checkups. You should remain under a doctor's care when taking VIRACEPT and should not change or stop treatment without first talking with your doctor.

What is VIRACEPT and how does it work?

VIRACEPT is used in the treatment of people with human immunodeficiency virus (HIV) infection. Infection with HIV leads to the destruction of CD4 T cells, which are important to the immune system. After a large number of CD4 cells have been destroyed, the infected person develops acquired immune deficiency syndrome (AIDS).

VIRACEPT works by blocking HIV protease (a protein-cutting enzyme), which is required for HIV to multiply. VIRACEPT has been shown to significantly reduce the amount of HIV in the blood. You should be aware, however, that the effect of VIRACEPT on HIV in the blood has not been correlated with long-term health benefits. Patients who took VIRACEPT also had significant increases in the number of CD4 cell count.

VIRACEPT is usually taken together with other antiretroviral drugs such as Retrovir® (zidovudine, AZT), Efavir® (lamivudine, 3TC), or Zerit® (stavudine, d4T). Taking VIRACEPT in combination with other antiretroviral drugs reduces the amount of HIV in the body (viral load) and raises CD4 counts.

VIRACEPT may be taken by adults, adolescents, and children 2 years of age or older. Studies in infants younger than 2 years of age are now taking place.

Does VIRACEPT cure HIV or AIDS?

VIRACEPT is not a cure for HIV infection or AIDS. The long-term effects of VIRACEPT are not known at this time. People taking VIRACEPT may still develop opportunistic infections or other conditions associated with HIV infection. Some of these conditions are pneumonia, herpes virus infections, Mycobacterium avium complex (MAC) infections, and Kaposi's sarcoma.

It is not known whether VIRACEPT will help you live longer or reduce the number of infections or other illnesses that may occur.

There is no proof that VIRACEPT can reduce the risk of transmitting HIV to others through sexual contact or blood contamination.

Who should or should not take VIRACEPT?

Together with your doctor, you need to decide whether VIRACEPT is appropriate for you. In making your decision, the following should be considered:

Allergies: If you have had a serious allergic reaction to VIRACEPT, you must not take VIRACEPT. You should also inform your doctor, nurse, or pharmacist of any known allergies to substances such as other medicines, foods, preservatives, or dyes.

If you are pregnant: The effects of VIRACEPT on pregnant women or their unborn babies are not known. If you are pregnant or plan to become pregnant, you should tell your doctor before taking VIRACEPT.

If you are breast-feeding: You should discuss with your doctor the best way to feed your baby. You should be aware that if your baby does not already have HIV, there is a chance that it can be transmitted through breast-feeding. **Women should not breast-feed if they have HIV.**

Children: VIRACEPT is available for the treatment of children 2 through 13 years of age with HIV. There is a powder form of VIRACEPT that can be mixed with milk, baby formula, or foods like pudding. Instructions on how to take VIRACEPT powder can be found in a later section that discusses how VIRACEPT Oral Powder should be prepared.

If you have liver disease: VIRACEPT has not been studied in people with liver disease. If you have liver disease, you should tell your doctor before taking VIRACEPT.

Other medical problems: Certain medical problems may affect the use of VIRACEPT. Some people taking protease inhibitors have developed new or more serious diabetes or high blood sugar. Some people with hemophilia have had increased bleeding. It is not known whether the protease inhibitors caused these problems. Be sure to tell your doctor if you have hemophilia types A and B, diabetes mellitus, or an increase in thirst and/or frequent urination.

Changes in body fat have been seen in some patients taking protease inhibitors. These changes may include increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the trunk. Loss of fat from the legs and arms may also happen. The cause and long-term health effects of these conditions are not known at this time.

Can VIRACEPT be taken with other medications?

VIRACEPT may interact with other drugs, including those you take without a prescription. You must discuss with your doctor any drugs that you are taking or are planning to take before you take VIRACEPT.

Drugs you should not take with VIRACEPT:

- Hismanal® (astemizole, for allergies)
- Propulsid® (cisapride, for heartburn)
- Cordarone® (amiodarone, for irregular heartbeat)
- Quinidine® (for irregular heartbeat), also known as Quinaglute®, Cardioquin®, Quindex®, and others
- Ergot derivatives (Cafegot® and others, for migraine headache)
- Halcion® (triazolam)
- Versed® (midazolam)

Taking the above drugs with VIRACEPT may cause serious and/or life-threatening adverse events.

- Rifampin® (for tuberculosis), also known as Rimactane®, Rifadin®, Rifater®, or Rifamate®

This drug reduces blood levels of VIRACEPT.

Dose reduction required if you take VIRACEPT with:

- Mycobutin® (rifabutin, for MAC); you will need to take a lower dose of Mycobutin.

A change of therapy should be considered if you are taking VIRACEPT with:

- Phenobarbital
- Phenytoin (Dilantin® and others)
- Carbamazepine (Tegretol® and others)

These agents may reduce the amount of VIRACEPT in your blood and make it less effective.

- Oral contraceptives ("the pill")

If you are taking the pill to prevent pregnancy, you should use a different type of contraception since VIRACEPT may reduce the effectiveness of oral contraceptives.

Special considerations

Before you take Viagra® (sildenafil) with VIRACEPT, talk to your doctor about possible drug interactions and side effects. If you take Viagra and VIRACEPT together, you may be at increased risk of side effects of Viagra such as low blood pressure, visual changes, and penile erection lasting more than 4 hours. If an erection lasts longer than 4 hours, you should seek immediate medical assistance to avoid permanent damage to your penis. Your doctor can explain these symptoms to you.

It is not recommended to take VIRACEPT with the cholesterol-lowering drugs Mevacor® (lovastatin) or Zorcor® (simvastatin) because of possible drug interactions. There is also an increased risk of drug interactions between VIRACEPT and Lipitor® (atorvastatin) and Baycol® (cerivastatin); talk to your doctor before you take either of these cholesterol reducing drugs with VIRACEPT.

How should VIRACEPT be taken with other anti-HIV drugs?

Taking VIRACEPT together with other anti-HIV drugs increases their ability to fight the virus. It also reduces the opportunity for resistant viruses to grow. Based on your history of taking other anti-HIV medicine, your doctor will direct you on how to take VIRACEPT and other anti-HIV medicines. These drugs should be taken in a certain order or at specific times. This will depend on how many times a day each medicine should be taken. It will also depend on whether it should be taken with or without food.

Nucleoside analogues: No drug interaction problems were seen when VIRACEPT was given with:

- Retrovir (zidovudine, AZT)
- Efavir (lamivudine, 3TC)
- Zerit (stavudine, d4T)
- Videx® (didanosine, ddl)

If you are taking both Videx (ddl) and VIRACEPT:

Videx should be taken without food, on an empty stomach. Therefore, you should take VIRACEPT with food one hour after or more than two hours before you take Videx.

Nonnucleoside reverse transcriptase inhibitors (NNRTIs):

When VIRACEPT is taken together with:

Viramune® (nevirapine)
The amount of VIRACEPT in your blood may be reduced. Studies are now taking place to learn about the safety of combining VIRACEPT with Viramune.

Sustiva™ (efavirenz)
The amount of VIRACEPT in your blood may be increased. A dose adjustment is not needed when VIRACEPT is used with Sustiva.

Other NNRTIs
VIRACEPT has not been studied with other NNRTIs.

Other protease inhibitors:

When VIRACEPT is taken together with:

Crixivan® (indinavir)
The amount of both drugs in your blood may be increased. Currently, there are no safety and efficacy data available from the use of this combination.

Norvir™ (ritonavir)
The amount of VIRACEPT in your blood may be increased. Currently, there are no safety and efficacy data available from the use of this combination.

Invirase® (saquinavir)
The amount of saquinavir in your blood may be increased. Currently, there are no safety and efficacy data available from the use of this combination.

What are the side effects of VIRACEPT?

Like all medicines, VIRACEPT can cause side effects. Most of the side effects experienced with VIRACEPT have been mild to moderate. Diarrhea is the most common side effect in people taking VIRACEPT, and most adult patients had at least mild diarrhea at some point during treatment. In clinical studies, about 14-20% of patients receiving VIRACEPT 750 mg (three tablets) three times daily or 1250 mg (five tablets) two times daily had four or more loose stools a day. In most cases, diarrhea can be controlled using antidiarrheal medicines, such as Imodium® A-D (loperamide) and others, which are available without a prescription.

Other side effects that occurred in 2% or more of patients receiving VIRACEPT include abdominal pain, asthenia, nausea, flatulence, and rash.

There were other side effects noted in clinical studies that occurred in less than 2% of patients receiving VIRACEPT. However, these side effects may have been due to other drugs that patients were taking or to the illness itself. Except for diarrhea, there were not many differences in side effects in patients who took VIRACEPT along with other drugs compared with those who took only the other drugs. For a complete list of side effects, ask your doctor, nurse, or pharmacist.

How should I take VIRACEPT?

VIRACEPT is available only with your doctor's prescription. Your doctor may prescribe the light blue VIRACEPT Tablets either as 1250 mg (five tablets) taken two times a day or as 750 mg (three tablets) taken three times a day. VIRACEPT should always be taken with a meal or a light snack.

Take VIRACEPT exactly as directed by your doctor. Do not increase or decrease any dose or the number of doses per day. Also, take this medicine for the exact period of time that your doctor has instructed. **Do not stop taking VIRACEPT without first consulting with your doctor, even if you are feeling better.**

Only take medicine that has been prescribed specifically for you. Do not give VIRACEPT to others or take medicine prescribed for someone else.

The dosing of VIRACEPT may be different for you than for other patients. **Follow the directions from your doctor, exactly as written on the label.** The amount of VIRACEPT in the blood should remain somewhat consistent over time. Missing doses will cause the concentration of VIRACEPT to decrease; therefore, **you should not miss any doses.** However, if you miss a dose, you should take the dose as soon as possible and then take your next scheduled dose and future doses as originally scheduled.

Dosing in adults (including children 14 years of age and older)

The recommended adult dose of VIRACEPT is 1250 mg (five tablets) taken two times a day or 750 mg (three tablets) taken three times a day. Each dose should be taken with a meal or light snack.

Dosing in children 2 to 13 years of age

The VIRACEPT dose in children depends on their weight. The recommended dose is 20 to 30 mg/kg (or 9 to 14 mg/pound) per dose, taken three times daily with a meal or light snack. This can be administered either in tablet form or, in children unable to take tablets, as VIRACEPT Oral Powder.

Dose instructions will be provided by the child's doctor. The dose will be given three times daily using the measuring scoop provided, a measuring teaspoon, or one or more tablets depending on the weight and age of the child. The amount of oral powder or tablets to be given to a child is described in the chart below.

Pediatric Dose to be Administered Three Times Daily				
Body Weight Kg	Lb	Number of Level Scoops*	Number of Level Teaspoons†	Number of Tablets
8.5 to <10.5	18.5 to <23	5	1 1/4	—
10.5 to <12	23 to <26.5	6	1 1/2	—
12 to <14	26.5 to <31	7	1 3/4	—
14 to <16	31 to <35	8	2	—
16 to <18	35 to <39.5	9	2 1/4	—
18 to <23	39.5 to <50.5	10	2 1/2	2
≥ 23	≥50.5	15	3 3/4	3

In measuring oral powder, the scoop or teaspoon should be level.

*1 level scoop contains 50 mg of VIRACEPT. Use only the scoop provided with your VIRACEPT bottle.

†1 level teaspoon contains 200 mg of VIRACEPT. Note: **A measuring teaspoon used for dispensing medication** should be used for measuring VIRACEPT Oral Powder. Ask your Pharmacist to make sure you have a medication dispensing teaspoon.

How should VIRACEPT Oral Powder be prepared?

The oral powder may be mixed with a small amount of water, milk, formula, soy formula, soy milk, dietary supplements, or dairy foods such as pudding or ice cream. Once mixed, the entire amount must be taken to obtain the full dose.

Do not mix the powder with any acidic foods or juice, such as orange or grapefruit juice, apple juice, or apple sauce, because this may create a bitter taste.

Once the powder is mixed, it may be stored at room temperature or refrigerated for up to 6 hours. Do not heat the mixed dose once it has been prepared.

Do not add water to bottles of oral powder.

VIRACEPT powder is supplied with a scoop for measuring. For help in determining the exact dose of powder for your child, please ask your doctor, nurse, or pharmacist.

VIRACEPT Oral Powder contains aspartame, a low-calorie sweetener, and therefore should not be taken by children with phenylketonuria (PKU).

How should VIRACEPT be stored?

Keep VIRACEPT and all other medicines out of the reach of children. Keep bottle closed and stored at room temperature (between 59°F and 86°F) away from sources of moisture such as a sink or other damp place. Heat and moisture may reduce the effectiveness of VIRACEPT.

Do not keep medicine that is out of date or that you no longer need. Be sure that if you throw any medicine away, it is out of the reach of children.

Discuss all questions about your health with your doctor. If you have questions about VIRACEPT or any other medication you are taking, ask your doctor, nurse, or pharmacist. You can also call 1.888.VIRACEPT (1.888.847.2237) toll free.

Call 1.888.VIRACEPT

VIRACEPT and Agouron are registered trademarks of Agouron Pharmaceuticals, Inc.
Copyright ©2000, Agouron Pharmaceuticals, Inc. All Rights reserved.



La Jolla, California, 92037, USA

L202-000

Rev. 12/13/99