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Research Triangle Park, NC 27709

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<b>VIRACEPT (VI-ra-cept) (nelfinavir mesylate) Tablets</b>	<b>PATIENT INFORMATION</b>	<b>VIRACEPT (VI-ra-cept) (nelfinavir mesylate) Oral Powder</b>
<p><b>Important: VIRACEPT can interact with other medicines and cause serious side effects. It is important to know the medicines that should not be taken with VIRACEPT. See the section “Do not take VIRACEPT if you:”</b></p>		
<p><b>What is VIRACEPT?</b>  VIRACEPT is a prescription HIV-1 medicine used with other HIV-1 medicines to treat human immunodeficiency virus (HIV-1) infection.  HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).  It is not known if VIRACEPT is safe and effective in children less than 2 years of age.</p>		
<p><b>Do not take VIRACEPT if you:</b></p> <ul style="list-style-type: none"> <li>• are taking any of the following medicines. VIRACEPT may cause serious life-threatening side effects or death when used with these medicines: <ul style="list-style-type: none"> <li>○ alfuzosin</li> <li>○ amiodarone</li> <li>○ cisapride</li> <li>○ ergot-containing medicines: <ul style="list-style-type: none"> <li>▪ dihydroergotamine</li> <li>▪ ergotamine</li> <li>▪ methylergonovine</li> </ul> </li> <li>○ lovastatin</li> <li>○ lurasidone</li> <li>○ midazolam, when taken by mouth for sedation</li> <li>○ pimozide</li> <li>○ quinidine</li> <li>○ rifampin</li> <li>○ sildenafil (Revatio®), when used for the treatment of pulmonary arterial hypertension (PAH)</li> <li>○ simvastatin</li> <li>○ St. John’s wort (<i>Hypericum perforatum</i>)</li> <li>○ triazolam</li> </ul> </li> </ul>		
<p><b>Before taking VIRACEPT, tell your healthcare provider about all of your medical conditions, including if you:</b></p> <ul style="list-style-type: none"> <li>• have liver problems</li> <li>• have kidney problems</li> <li>• have phenylketonuria. VIRACEPT Oral Powder contains aspartame.</li> <li>• have high blood sugar (diabetes)</li> <li>• have hemophilia</li> <li>• are pregnant or plan to become pregnant. VIRACEPT may harm your unborn baby. <ul style="list-style-type: none"> <li>○ Tell your healthcare provider right away if you become pregnant during treatment with VIRACEPT.</li> <li>○ Hormonal forms of birth control, such as injections, vaginal rings or implants, contraceptive patches, and some birth control pills may not work during treatment with VIRACEPT. Talk to your healthcare provider about forms of birth control that may be used during treatment with VIRACEPT.</li> <li>○ <b>Pregnancy Registry.</b> There is a pregnancy registry for women who take VIRACEPT during pregnancy. The purpose of the registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry.</li> </ul> </li> <li>• are breastfeeding or plan to breastfeed. <b>Do not breastfeed if you take VIRACEPT.</b> <ul style="list-style-type: none"> <li>○ You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.</li> <li>○ VIRACEPT can pass into your breast milk.</li> <li>○ Talk to your healthcare provider about the best way to feed your baby.</li> </ul> </li> </ul> <p><b>Tell your healthcare provider about all the medicines you take</b>, including prescription and over-the-counter medicines, vitamins and herbal supplements. Some medicines interact with VIRACEPT. Keep a list of your medicines to show your healthcare provider and pharmacist.</p> <ul style="list-style-type: none"> <li>• You can ask your healthcare provider or pharmacist for a list of medicines that interact with VIRACEPT.</li> <li>• <b>Do not start taking a new medicine without telling your healthcare provider.</b> Your healthcare provider can tell you if it is safe to take VIRACEPT with other medicines.</li> </ul>		

- Especially tell your healthcare provider if you take medicines that contain didanosine. Take VIRACEPT with food one hour after or more than two hours before you take didanosine.

### How should I take VIRACEPT?

- **You should stay under a healthcare provider's care during treatment with VIRACEPT.**
- **Take VIRACEPT every day exactly as prescribed by your healthcare provider.**
- Do not change your dose of VIRACEPT or stop treatment without talking to your healthcare provider first.
- **Take VIRACEPT with a meal.**
- VIRACEPT is usually taken 2 or 3 times each day. Your healthcare provider will tell you how much VIRACEPT to take and when to take it.
- If your child is taking VIRACEPT, your child's healthcare provider will decide the right dose based on your child's weight.
- VIRACEPT Tablets are film-coated to help make the tablets easier to swallow.
- If you or your child are unable to swallow the tablets:
  - You may dissolve the tablets in a small amount of water. Once the tablets are dissolved, the liquid will be cloudy.
  - Mix the cloudy liquid well, and then drink it right away.
  - Rinse the glass with water and drink the water to ensure that you take the full dose of VIRACEPT.
- If you **miss a dose** of VIRACEPT, take it as soon as possible. If you skip a dose, do not double the next dose.
- If you **take too much VIRACEPT**, call your healthcare provider or go to the nearest hospital emergency room right away.
- Do not run out of VIRACEPT. Get your VIRACEPT refilled from your healthcare provider or pharmacy before you run out.

### How should VIRACEPT Oral Powder be prepared?

- Your healthcare provider should tell you how much VIRACEPT Oral Powder to use.
- VIRACEPT Oral Powder comes with a scoop for measuring. Ask your healthcare provider or pharmacist for help measuring the correct amount of VIRACEPT Oral Powder.
- Do not mix VIRACEPT Oral Powder in the container that it comes in. Measure the correct amount of VIRACEPT Oral Powder into a cup.
- You may mix VIRACEPT Oral Powder with a small amount of water, milk, formula, soy formula, soy milk, or liquid dietary supplements.
- You should not mix VIRACEPT Oral Powder with acidic food or juice, such as orange juice, apple juice, or applesauce because the mixture may taste bitter.
- Your child should drink all of the mixture to be sure that the entire dose of VIRACEPT is taken.
- If your child does not take the dose right away, store in the refrigerator until you are ready to use it. Do not store a mixed dose of VIRACEPT Oral Powder for more than 6 hours.

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

#### **VIRACEPT can cause serious side effects, including:**

- **Diabetes and high blood sugar (hyperglycemia).** Some people who take protease inhibitors including VIRACEPT can get high blood sugar, develop diabetes, or your diabetes can get worse. Some people have had to start taking medicine to treat diabetes or have had to change their diabetes medicine. Tell your healthcare provider if you notice an increase in thirst or urinate often while taking VIRACEPT.
- **Increased bleeding in people with hemophilia.** Some people with hemophilia have increased bleeding with protease inhibitors including VIRACEPT.
- **Changes in body fat.** These changes can happen in people taking HIV-1 medicines. The changes may include an increased amount of fat in the upper back and neck ("buffalo hump"), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these conditions are not known.

- **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. Call your healthcare provider right away if you start having new symptoms after starting your HIV-1 medicine.

The most common side effects of VIRACEPT in adults and adolescents (13 years of age and older) include:

- diarrhea
- nausea
- rash
- gas

The most common side effects of VIRACEPT in children (2 years of age to less than 13 years of age) include:

- diarrhea
- low white blood cell count (leukopenia and neutropenia)
- rash
- loss of appetite
- stomach-area (abdominal) pain

These are not all the possible side effects of VIRACEPT.

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 VIRACEPT?**

- Store VIRACEPT Tablets and Oral Powder at room temperature, between 59°F to 86°F (15°C to 30°C).
- Store VIRACEPT in the original container.
- Keep the container closed tightly.

**Keep VIRACEPT and all medicines out of the reach of children.**

#### **General information about the safe and effective use of VIRACEPT.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use VIRACEPT for a condition for which it was not prescribed. Do not give VIRACEPT to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about VIRACEPT that is written for health professionals.

#### **What are the ingredients in VIRACEPT?**

**Active ingredient:** nelfinavir mesylate

**Tablet inactive ingredients:** calcium silicate, crospovidone, magnesium stearate, hypromellose, and triacetin. In addition, the 250 mg tablet contains FD&C blue #2 powder and the 625 mg tablet contains colloidal silicon dioxide.

**Oral powder inactive ingredients:** microcrystalline cellulose, maltodextrin, dibasic potassium phosphate, crospovidone, hypromellose, aspartame, sucrose palmitate, and natural and artificial flavor.

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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