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Agouron Pharmaceuticals, Inc.

VIRACEPT®

Patient Prescribing Information

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VIRACEPT® (nelfinavir mesylate) TABLETS and ORAL POWDER

ALERT: Find out about medicines that should NOT be taken with VIRACEPT. Please also read the section “MEDICINES YOU SHOULD NOT TAKE WITH VIRACEPT”.

Patient Information

VIRACEPT® (VI-ra-cept)

Generic Name: nelfinavir (nel-FIN-na-veer) mesylate

Please read this information carefully before taking VIRACEPT. Also, please read this leaflet each time you renew the prescription, in case anything has changed. This is a summary and not a replacement for a careful discussion with your healthcare provider. You and your healthcare provider should discuss VIRACEPT when you start taking this medication and at regular checkups. You should remain under a healthcare provider’s care when taking VIRACEPT and should not change or stop treatment without first talking with your healthcare provider.

What is VIRACEPT and how does it work?

VIRACEPT is a type of medicine called an HIV (human immunodeficiency virus) protease (PRO-tee-ase) inhibitor. VIRACEPT is always used in combination with other antiretroviral drugs in the treatment of people with HIV infection. VIRACEPT is for adults and for children 2 years of age and older.

Infection with HIV leads to the destruction of CD4 (T) cells, which are important to the immune system. After a large number of CD4 (T) 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. Although VIRACEPT is not a cure for HIV or AIDS, VIRACEPT can help reduce your risk for death and illness associated with HIV. Patients who took VIRACEPT also had significant increases in the number of CD4 (T) cells.

Does VIRACEPT cure HIV or AIDS?

VIRACEPT is not a cure for HIV infection or AIDS. 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.

Does VIRACEPT reduce the risk of passing HIV to others?

VIRACEPT does not reduce the risk of transmitting HIV to others through sexual contact or blood contamination. Continue to practice safe sex and do not use or share dirty needles.

How should I take VIRACEPT?

- You should stay under a healthcare provider's care when taking VIRACEPT. Do not change your treatment or stop treatment without first talking with your healthcare provider.
- You must take VIRACEPT every day exactly as your healthcare provider prescribed it. Follow the directions from your healthcare provider, exactly as written on the label.
- Dosing in adults (including children 14 years of age and older): The recommended adult dose of VIRACEPT is 1250 mg (five 250 mg tablets or two 625 mg tablets) taken two times a day or 750 mg (three 250 mg tablets) taken three times a day. **Each dose should always be taken with a meal** to help achieve higher VIRACEPT levels. VIRACEPT Tablets are film-coated to help make the tablets easier to swallow.
- Dosing in children 2 years of age and older: The VIRACEPT dose in children depends on their weight. The recommended oral dose of VIRACEPT oral powder or 250 mg tablets is 45 to 55 mg/kg twice daily or 25 to 35 mg/kg three times daily. All doses should be taken **with a meal**. Children who cannot swallow tablets may take VIRACEPT Oral Powder or crushed tablets.
- If you or your child is unable to swallow the tablets, dissolve the tablets in a small amount of water. Once dissolved, mix the cloudy liquid well, and consume immediately. The glass should be rinsed with water and the rinse swallowed to ensure the entire dose is consumed.
- **Do not change your dose or stop taking VIRACEPT without first consulting with your healthcare provider.**
- When your VIRACEPT supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to antiretroviral medications, including VIRACEPT, but there are other antiretroviral treatment options. Talk to your healthcare provider about how to optimize your long-term treatment.
- Be sure to set up a schedule and follow it carefully.
- Only take medicine that has been prescribed specifically for you. Do not give VIRACEPT to others or take medicine prescribed for someone else.

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. If the mixture is not consumed immediately, it must be stored

under refrigeration, but storage must not exceed 6 hours. Do **not** heat the mixed dose once it has been prepared.

- Do **not** mix the powder with any acidic food or juice, such as orange or grapefruit juice, apple juice, or apple sauce, because this may create a bitter taste.
- 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, pharmacist, or other healthcare provider.

What should I do if I miss a dose?

If you forget to take a dose of VIRACEPT, take it as soon as possible. However, if you skip the dose entirely, do not double the next dose. If you forget a lot of doses, talk to your healthcare provider about how you should continue taking your medicine.

What happens if I take too much VIRACEPT?

If you suspect that you took more than the prescribed dose of this medicine, contact your local poison control center or emergency room immediately.

Who should not take VIRACEPT?

Together with your healthcare provider, you need to decide whether VIRACEPT is appropriate for you.

- **Do not take VIRACEPT if you are taking certain medicines.** These could cause serious side effects that could cause death. Before you take VIRACEPT, you must tell your healthcare provider about all medicines you are taking or are planning to take. These include prescription and non-prescription medicines and herbal supplements.

For more information about medicines you should not take with VIRACEPT, please read the section titled “**MEDICINES YOU SHOULD NOT TAKE WITH VIRACEPT.**”

- **Do not take VIRACEPT if you have an allergy to VIRACEPT.** Also tell your healthcare provider if you have any known allergies to other medicines, foods, preservatives, or dyes.
- **Tell your healthcare provider if you are pregnant or plan to become pregnant.** The effects of VIRACEPT on pregnant women or their unborn babies are not known.
- If you are breast-feeding, it is very important that you speak with your healthcare provider about the best way to feed your baby. If your baby does not already have HIV, there is a chance that it can be transmitted through breast-feeding. **The Centers for Disease Control and Prevention recommends that women with HIV do not breast-feed.**
- **Talk with your healthcare provider if you have liver or kidney disease.** VIRACEPT has not been extensively studied in people with liver or kidney disease.

- **Certain medical problems may affect the use of VIRACEPT.** Be sure to tell your healthcare provider of any other medical problems you may have.

Can VIRACEPT be taken with other medications?

VIRACEPT may interact with other drugs, including those you take without a prescription. You must tell your healthcare provider about all medicines you are taking or planning to take before you take VIRACEPT. It is a good idea to keep a complete list of all the medicines that you take, including non-prescription medicines, herbal remedies and supplements and street drugs. Update this list when medicines are added or stopped. Give copies of this list to all of your healthcare providers **every** time you visit or fill a prescription.

MEDICINES YOU SHOULD NOT TAKE WITH VIRACEPT:

Do not take the following drugs because they can cause serious problems or death if taken with VIRACEPT:

- Cordarone[®] (amiodarone) (for irregular heartbeat)
- Orap[®] (pimozide) (for seizures)
- Quinidine[®] (for irregular heartbeat), also known as Quinaglute[®], Cardioquin[®], Quinidex[®], and others
- D.H.E. 45[®] Injection, Ergomar[®], Migranal[®], Wigraine[®] and Cafegot[®] (for migraine headaches) and Methergine[®] (for bleeding after childbirth)
- Halcion[®] (triazolam) (for sleep problem)
- Versed[®] (midazolam) (sedative hypnotic)

Do not take the following medicines when you take VIRACEPT. They may reduce the levels of VIRACEPT in the blood and make it less effective. Talk with your healthcare provider if you are currently taking these medicines because other medicines may have to be given to take their place:

- **Prilosec[®] (omeprazole) (for stomach acid reduction)**
- Rifampin[®] (also known as Rimactane[®], Rifadin[®], Rifater[®], or Rifamate[®]) (for tuberculosis)
- Phenobarbital (for seizures)
- Tegretol[®] (carbamazepine) (for seizures)

Do not take VIRACEPT with St. John's wort (*hypericum perforatum*), an herbal product sold as a dietary supplement, or products containing St. John's wort. Talk with your healthcare provider if you are taking or planning to take St. John's wort. Taking St. John's wort may decrease VIRACEPT levels and lead to increased viral load and possible resistance to VIRACEPT.

Do not take VIRACEPT with cholesterol-lowering medicines Mevacor[®] (lovastatin) or Zocor[®] (simvastatin) because of possible serious reactions. There is also an increased risk of drug interactions between VIRACEPT and Lipitor[®] (atorvastatin) and Lescol[®] (fluvastatin); talk to your healthcare provider before you take any of these cholesterol-reducing medicines with VIRACEPT.

Talk to your healthcare provider before you start taking any new prescription or non-prescription medicines or herbal supplements with VIRACEPT.

Medicines that require dose adjustments:

It is possible that your healthcare provider may need to increase or decrease the dose of other medicines when you are also taking VIRACEPT.

BEFORE YOU TAKE VIAGRA[®] (SILDENAFIL) WITH VIRACEPT, TALK TO YOUR HEALTHCARE PROVIDER 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 HEALTHCARE PROVIDER CAN EXPLAIN THESE SYMPTOMS TO YOU.

- **If you are taking both didanosine (Videx[®]) and VIRACEPT:**
YOU SHOULD TAKE VIRACEPT WITH FOOD ONE HOUR AFTER OR MORE THAN TWO HOURS BEFORE YOU TAKE VIDEX BUFFERED TABLETS.
- IF YOU ARE TAKING ORAL CONTRACEPTIVES ("THE PILL") TO PREVENT PREGNANCY, YOU SHOULD USE AN ADDITIONAL OR DIFFERENT TYPE OF CONTRACEPTION SINCE VIRACEPT MAY REDUCE THE EFFECTIVENESS OF ORAL CONTRACEPTIVES.
- **Non-nucleoside reverse transcriptase inhibitors (NNRTIs):** RESCRIPTOR[®] (delavirdine) may increase the amount of VIRACEPT in your blood and VIRACEPT may lower the amount of RESCRIPTOR in your blood.
- **Protease Inhibitors (PIs):** VIRACEPT may increase the amount of Crixivan[®] (indinavir), Norvir[®] (ritonavir), and Invirase[®] or Fortovase[®] (saquinavir) in your blood. As a result, your healthcare provider may choose to lower the dose of VIRACEPT or one of these other medicines or monitor certain lab tests if VIRACEPT is taken in combination with one or more of these other medicines.
- If you are taking Mycobutin[®] (rifabutin), your healthcare provider may lower the dose of Mycobutin.
- If you are taking Dilantin[®] (phenytoin), your healthcare provider will need to monitor the levels of phenytoin in your blood and may need to adjust the dose of phenytoin.
- Other Special considerations

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

What are the possible side effects of VIRACEPT?

- This list of side effects is not complete. If you have questions about side effects, ask your healthcare provider, nurse, or pharmacist. You should report any new or continuing symptoms to your healthcare provider right away. Your healthcare provider may be able to help you manage these 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 15-20% of patients receiving VIRACEPT 750 mg (three 250 mg tablets) three times daily or 1250 mg (five 250 mg

tablets or two 625 mg tablets) two times daily had four or more loose stools a day. Diarrhea may be more common in patients receiving the 625 mg formulation. In most cases, VIRACEPT-associated diarrhea can be controlled using antidiarrheal medicines, such as Imodium[®] A-D (loperamide).

- Other side effects that occurred in 3-7% of patients receiving VIRACEPT include nausea, gas, and rash.
- The side effects observed in children and adults receiving VIRACEPT are similar. Diarrhea was also the most common side effect seen in children. Some children experienced low white blood cells (leukopenia/neutropenia), which resolved without treatment interruption in most cases.
- Diabetes and high blood sugar (hyperglycemia) occur in patients taking protease inhibitors such as VIRACEPT. Some patients had diabetes before starting protease inhibitors, others did not. Some patients needed changes in their diabetes medicine. Others needed new diabetes medicine after starting their VIRACEPT medicine.
- Changes in body fat have been seen in some patients taking antiretroviral therapy. 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, arms and face may also happen. The cause and long-term health effects of these conditions are not known at this time.
- Some patients with hemophilia have increased bleeding with protease inhibitors.
- There were other side effects, some of them serious, 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.
- Before you start using any medicine, talk with your healthcare provider about what to expect and discuss ways to reduce the side effects you may have.

How should VIRACEPT be stored?

- Keep VIRACEPT and all other medicines out of the reach of children.
- Keep bottle closed and store 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.
- Store in original container.

General advice about prescription medicines

NDA 20-778/S-025

NDA 20-779/S-046

NDA 21-503/S-007

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

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