HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use VIRACEPT safely and effectively. See full prescribing information for VIRACEPT.

VIRACEPT® (nelfinavir mesylate) Tablets, for oral use
VIRACEPT® (nelfinavir mesylate) Oral Powder, for oral use
Initial U.S. Approval: 1997

----------RECENT MAJOR CHANGES----------
Contraindications (4) 9/2016

----------INDICATIONS AND USAGE----------
VIRACEPT is a protease inhibitor indicated for the treatment of HIV-1 infection in combination with other antiretroviral agents. (1)

----------DOSAGE AND ADMINISTRATION----------
- See full prescribing information for administration instructions (2)
- Adults and adolescents 13 years and older (tablets): 1250 mg twice daily or 750 mg three times daily with a meal (2.1)
- Children 2 to less than 13 years (oral powder or 250 mg tablets): 45 to 55 mg/kg twice daily or 25 to 35 mg/kg three times daily with a meal. Refer to Tables 1 and 2 of the full prescribing information for specific dosing guidelines based on age and body weight (2.2)

----------DOSAGE FORMS AND STRENGTHS----------
- Tablet: 250 mg, 625 mg nelfinavir free base (3)
- Oral Powder: 50 mg/g nelfinavir free base (3)

----------CONTRAINDICATIONS----------
- Coadministration with drugs that are highly dependent on CYP3A for clearance and which elevated concentrations are associated with serious and/or life-threatening events (4)

----------WARNINGS AND PRECAUTIONS----------
ALERT: Find out about medicines that should not be taken with VIRACEPT.
- The concomitant use of VIRACEPT and certain other drugs may result in known or potentially significant drug interactions. Consult the full prescribing information prior to and during treatment for potential drug interactions (5.1, 7.3)
- Hepatic impairment: should not be used in patients with either moderate or severe hepatic impairment (2.4, 5.2)
- Phenylketonuria: the oral powder contains 11.2 mg phenylalanine per gram of powder (5.3)
- Diabetes mellitus/hyperglycemia: new onset or exacerbation of pre-existing diabetes mellitus and hyperglycemia reported with protease inhibitors. In some cases after treatment discontinuation, hyperglycemia persisted (5.4)
- Hemophilia: increased bleeding, including spontaneous skin hematomas and hemarthrosis reported with protease inhibitors. In more than half of the cases, protease inhibitors was continued or reintroduced (5.5)
- Fat redistribution: observed with antiretroviral therapy (5.6)
- Immune reconstitution syndrome: reported with combination antiretroviral therapy, including VIRACEPT. Patients may develop an inflammatory response to indolent or residual opportunistic infections (5.7)

----------ADVERSE REACTIONS----------
- Most common adverse reactions (≥2%) of moderate or severe intensity in adults and adolescents (13 years and older) are diarrhea, nausea, rash, and flatulence (6.1).
- Most common adverse reactions in pediatric patients (2 to less than 13 years) are diarrhea, leukopenia/neutropenia, rash, anorexia, and abdominal pain. (6.2)

To report SUSPECTED ADVERSE REACTIONS, contact Pfizer Inc at 1-800-438-1985 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------
- Co-administration of **VIRACEPT** with other **drugs** (**CYP3A** substrates) can alter the concentration of these other **drugs**, and other drugs (inhibitors and/or inducers of CYP3A or CYP2C19) may alter the concentrations of nelfinavir. The potential drug-drug concentrations must be considered prior to and during therapy (4, 7, 12.3)
- VIRACEPT should be given with food one hour after or more than 2 hours before didanosine (7)

----------USE IN SPECIFIC POPULATIONS----------
- Use during pregnancy if the potential benefit justifies the potential risk to the fetus (8.1)
- Nursing mothers: should not breast-feed their infants (8.3)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 9/2016

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

VIRACEPT in combination with other antiretroviral agents is indicated for the treatment of HIV-1 infection.

2 DOSAGE AND ADMINISTRATION

2.1 Adults and Adolescents (13 years and older)

The recommended dose is 1250 mg (five 250 mg tablets or two 625 mg tablets) twice daily or 750 mg (three 250 mg tablets) three times daily. VIRACEPT should be taken with a meal. Patients unable to swallow the 250 or 625 mg tablets may dissolve the tablets in a small amount of water *[see Dosage and Administration (2.3)]*.

2.2 Pediatric Patients (2 to less than 13 years)

In children 2 years of age and older, 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**. Doses higher than the adult maximum dose of 2500 mg per day have not been studied in children.

For children unable to swallow tablets, VIRACEPT 250 mg tablet(s) may be dissolved in a small amount of water or, VIRACEPT Oral Powder may be administered *[see Dosage and Administration (2.3)]*.

The healthcare provider should assess appropriate formulation and dosage for each patient. Tables 1 and 2 provide dosing guidelines for VIRACEPT tablets and powder based on age and body weight.

Table 1:
Dosing Table for Children 2 to less than 13 years of age (tablets)

Body weight **Kg**	**Twice daily (BID)** **45 – 55 mg/kg** **≥2 years**	**Three times daily (TID)** **25 – 35 mg/kg** **≥2 years**
	Number of tablets **(250 mg)**	**Number of tablets** **(250 mg)**
10 – 12	2	1
13 – 18	3	2
19 – 20	4	2
≥21	4 – 5*	3†

* For BID dosing, the maximum dose per day is 5 tablets BID
† For TID dosing, the maximum dose per day is 3 tablets TID

Table 2:
Dosing Table for Children 2 to less than 13 years of age (powder)

Body weight	**Twice daily (BID) 45 – 55 mg/kg**		**Three times daily (TID) 25 – 35 mg/kg**	
Kg	Scoops of powder (50 mg/1 g)	Teaspoons* of powder	Scoops of powder (50 mg/1 g)	Teaspoons* of powder
9.0 to <10.5	10	2½	6	1½
10.5 to <12	11	2¾	7	1¾
12 to <14	13	3¼	8	2
14 to <16	15	3¾	9	2¼
16 to <18	Not recommended†	Not recommended†	10	2½
18 to <23	Not recommended†	Not recommended†	12	3
≥23	Not recommended†	Not recommended†	15	3¾

* If a teaspoon is used to measure VIRACEPT oral powder, 1 level teaspoon contains 200 mg of VIRACEPT (4 level scoops equals 1 level teaspoon)
† Use VIRACEPT 250 mg tablet

2.3 Method of Administration

For Patients Unable to Swallow Viracept Tablets

- Place VIRACEPT tablet(s) in small amount of water.
- Once dissolved, mix the cloudy liquid well, and consume it immediately.
- The glass should be rinsed with water and the rinse swallowed to ensure the entire dose is consumed.

Viracept Oral Powder

- Mix VIRACEPT Oral Powder with a small amount of water, milk, formula, soy formula, soy milk, or dietary supplements
- Once mixed, the entire contents must be consumed in order 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.
- Acidic food or juice (e.g., orange juice, apple juice, or apple sauce) are not recommended for mixing VIRACEPT Oral Powder because the combination may result in a bitter taste.
- VIRACEPT Oral Powder should not be reconstituted with water in its original container.

2.4 Hepatic Impairment

VIRACEPT can be used in patients with mild hepatic impairment without any dose adjustment. VIRACEPT should not be used in patients with either moderate or severe hepatic impairment *[see Warnings and Precautions (5.2), Use in Specific Populations (8.6), and Clinical Pharmacology (12.3)]*.

3 DOSAGE FORMS AND STRENGTHS

VIRACEPT 250 mg Tablet: Light-blue, capsule-shaped tablets with a clear film coating engraved with “VIRACEPT” on one side and “250 mg” on the other.

VIRACEPT 625 mg Tablet: White oval tablet with a clear film coating engraved with "V" on one side and "625" on the other.

VIRACEPT Oral Powder: Off-white powder containing 50 mg (as nelfinavir-free base) in each level scoopful (1 gram).

4 CONTRAINDICATIONS

Coadministration of VIRACEPT is contraindicated with drugs that are highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with serious and/or life-threatening events. These drugs and other contraindicated drugs (which may lead to reduced efficacy of nelfinavir) are listed in Table 3 *[also see Drug Interactions (7), Table 6*].

Table 3:
Drugs That Are Contraindicated With VIRACEPT

Drug Class	**Drugs Within Class That Are Contraindicated With VIRACEPT**	**Clinical Comment**
Alpha 1-adrenoreceptor antagonist	Alfuzosin	Potentially increased alfuzosin concentrations can result in hypotension.
Antiarrhythmics	Amiodarone, quinidine	Potential for serious and/or life-threatening cardiac arrhythmia.
Antimycobacterial Agents	Rifampin	Plasma concentrations of nelfinavir can be reduced by concomitant use of rifampin. This may lead to loss of therapeutic effect and possible development of resistance to VIRACEPT or other coadministered antiretroviral agents.
Antipsychotics	Lurasidone Pimozide	Potential for serious and/or life-threatening reactions. Potential for serious and/or life threatening reactions such as cardiac arrhythmias.
Ergot Derivatives	Dihydroergotamine, ergotamine, methylergonovine	Potential for serious and/or life threatening reactions such as ergot toxicity characterized by peripheral vasospasm and ischemia of the extremities and other tissues.
GI Motility Agent	Cisapride	Potential for serious and/or life threatening reactions such as cardiac arrhythmias.
Herbal products	St. John's wort (*Hypericum perforatum*)	Plasma concentrations of nelfinavir can be reduced by concomitant use of the herbal preparation St. John’s wort. This may lead to loss of therapeutic effect and possible development of resistance to VIRACEPT or other coadministered antiretroviral agents.
HMG-CoA Reductase Inhibitors	Lovastatin, Simvastatin	Potential for serious reactions such as myopathy including rhabdomyolysis.
PDE5 Inhibitors	Sildenafil (Revatio®) [for treatment of pulmonary arterial hypertension][a]	A safe and effective dose has not been established when used with nelfinavir. There is increased potential for sildenafil-associated adverse events (which include visual disturbances,

		hypotension, prolonged erection, and syncope).
Sedative/Hypnotics	Triazolam, oral midazolam	Potential for serious and/or life threatening reactions such as prolonged or increased sedation or respiratory depression.

[a] See *Drug Interactions, Table 6* for coadministration of sildenafil and tadalafil when dosed for erectile dysfunction.

5 WARNINGS AND PRECAUTIONS

ALERT: Find out about medicines that should not be taken with VIRACEPT. This statement is included on the product's bottle label.

5.1 Risk of Serious Adverse Reactions Due to Drug Interactions

Initiation of VIRACEPT, a CYP3A inhibitor, in patients receiving medications metabolized by CYP3A or initiation of medications metabolized by CYP3A in patients already receiving VIRACEPT, may increase plasma concentrations of medications metabolized by CYP3A. Initiation of medications that inhibit or induce CYP3A may increase or decrease concentrations of VIRACEPT, respectively. These interactions may lead to:

- Clinically significant adverse reactions, potentially leading to severe, life threatening, or fatal events from greater exposures of concomitant medications.
- Clinically significant adverse reactions from greater exposures of VIRACEPT.
- Loss of therapeutic effect of VIRACEPT and possible development of resistance.

See Table 6 for steps to prevent or manage these possible and known significant drug interactions, including dosing recommendations *[see Drug Interactions (7)]*. Consider the potential for drug interactions prior to and during VIRACEPT therapy; review concomitant medications during VIRACEPT therapy; and monitor for the adverse reactions associated with the concomitant medications *[see Contraindications (4) and Drug Interactions (7)]*.

5.2 Hepatic Impairment

VIRACEPT should not be used in patients with either moderate or severe hepatic impairment (Child-Pugh B or C, score greater than or equal to 7) *[see Dosage and Administration (2.4) and Clinical Pharmacology (12.3)]*.

5.3 Phenylketonurics

Viracept Oral Powder contains phenylalanine, a component of aspartame. Each gram of VIRACEPT powder contains 11.2 mg phenylalanine. Phenylalanine can be harmful to patients with phenylketonuria.

5.4 Diabetes Mellitus/Hyperglycemia

New onset diabetes mellitus, exacerbation of pre-existing diabetes mellitus and hyperglycemia have been reported during post-marketing surveillance in HIV-infected patients receiving protease inhibitor therapy. Some patients required either initiation or dose adjustments of insulin or oral hypoglycemic agents for treatment of these events. In some cases diabetic ketoacidosis has occurred. In those patients who discontinued protease inhibitor therapy, hyperglycemia persisted in some cases. Because these events have been reported voluntarily during clinical practice, estimates of frequency cannot be made and a causal relationship between protease inhibitor therapy and these events has not been established.

5.5 Hemophilia

There have been reports of increased bleeding, including spontaneous skin hematomas and hemarthrosis, in patients with hemophilia type A and B treated with protease inhibitors. In some patients, additional factor VIII was given. In more than half of the reported cases, treatment with protease inhibitors was continued or reintroduced. A causal relationship has not been established.

5.6 Fat Redistribution

Redistribution/accumulation of body fat including central obesity, dorsocervical fat enlargement ("buffalo hump"), peripheral wasting, facial wasting, breast enlargement, and "cushingoid appearance" have been observed in patients receiving antiretroviral therapy. The mechanism and long-term consequences of these events are currently unknown. A causal relationship has not been established.

5.7 Immune Reconstitution Syndrome

Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy, including VIRACEPT. During the initial phase of combination antiretroviral treatment, patients whose immune system responds may develop an inflammatory response to indolent or residual opportunistic infections [such as *Mycobacterium avium* infection, cytomegalovirus, *Pneumocystis jiroveci* pneumonia (PCP), or tuberculosis], which may necessitate further evaluation and treatment.

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