

PART III: CONSUMER INFORMATION

PR VIRACEPT®
Nelfinavir tablets,
250 mg, 625 mg
(as nelfinavir mesylate)

Nelfinavir powder, 50 mg/g
(as nelfinavir mesylate)

This leaflet is part III of a three-part "Product Monograph" published when VIRACEPT was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about VIRACEPT. Your doctor and pharmacist are your primary sources of information about your health and the medicine you take. Consult with your doctor or pharmacist if you have questions about your health, any medication you take, or the information given here.

ABOUT THIS MEDICATION

What the medication is used for:

VIRACEPT is the brand name of the antiviral agent, nelfinavir mesylate. It is a member of a class of drugs called protease inhibitors. VIRACEPT is an important part of your anti-HIV therapy. It is active against the Human Immunodeficiency Virus (HIV), helping to reduce the number of HIV particles in blood.

Your doctor has prescribed VIRACEPT for you because you have HIV infection. HIV infection is a disease spread by contact with blood or sexual contact with an infected person.

VIRACEPT should be taken in combination with other antiretroviral agents. This combination has been shown to reduce significantly the number of HIV particles in the blood and to increase significantly circulating CD₄ cells.

This product has been prescribed for you personally, and you should not pass it on to others.

VIRACEPT is not a cure for HIV infection or AIDS. People taking VIRACEPT may still develop opportunistic infections or other illnesses associated with HIV disease. Some of these conditions are pneumonia, herpes virus infections, *Mycobacterium avium* complex (MAC) infections, and Kaposi's sarcoma. You should, therefore, remain under the care of your doctor while taking VIRACEPT.

Treatment with VIRACEPT has not been shown to reduce the risk of transmission of HIV to others through sexual contact or blood contamination. Continue to practice safer sex and do not reuse or share needles. Even when you are on the anti-HIV medications and your HIV viral load is "undetectable", you still have HIV in your body and you can still pass HIV to

others. It is very important to take precautions to avoid passing HIV to others.

What it does:

VIRACEPT is a medicine which interferes with the action of an HIV protease enzyme, to prevent normal viral protein formation. This interference creates immature, non-infectious viral particles which helps reduce the infection.

When it should not be used:

- If you are allergic or hypersensitive to nelfinavir or any of the components in the product (see **What the important nonmedicinal ingredients are**)

- If you are taking one or more of the following drugs:

Drug class	Drugs *
- gastrointestinal prokinetic	cisapride
- antiarrhythmics	amiodarone, quinidine
- ergot derivatives	dihydroergotamine, ergonovine, ergotamine, methylergonovine
- sedative/hypnotics	midazolam, triazolam
- HMG-CoA reductase inhibitors	lovastatin, simvastatin
- herbal products	St. John's Wort (<i>hypericum perforatum</i>)
- alpha 1-adrenoceptor antagonist	alfuzosin
- PDE-5 inhibitors	sildenafil when used to treat pulmonary arterial hypertension (PAH)
- antimycobacterial agents	rifampin
- Antipsychotics	lurasidone; pimozide,

* is no longer marketed in Canada

What is the medicinal ingredient:

Nelfinavir mesylate

What the important nonmedicinal ingredients are:

Crospovidone. Other non-medicinal ingredients present in VIRACEPT film-coated tablets include calcium silicate, magnesium stearate, hypromellose and triacetin. In addition the 625 mg tablet contains colloidal silicon dioxide and the 250 mg tablet contains FD&C blue #2 powder.

Other non-medicinal ingredients present in VIRACEPT oral powder include microcrystalline cellulose, maltodextrin, dibasic potassium phosphate, hydroxypropyl methylcellulose, aspartame, sucrose palmitate, and natural and artificial flavour.

What dosage forms it comes in:

Film-coated Tablets - 250 mg and 625 mg nelfinavir (from nelfinavir mesylate);

Oral Powder - 50 mg/g nelfinavir (from nelfinavir mesylate)

WARNINGS AND PRECAUTIONS

Tell your health care provider before taking VIRACEPT if:

- you have any medical problems, including liver disease, bleeding problems (hemophilia), or diabetes
- You are taking any medications including nonprescription, herbal or street drugs, natural health products as many drugs may interfere with the action of VIRACEPT, or VIRACEPT may interfere with these other drugs. (See **Interactions with this medication** section)
- You are pregnant or planning to become pregnant. VIRACEPT is not recommended for use in pregnant women. If you take VIRACEPT while pregnant, talk to your doctor about how you can be included in the Antiretroviral Pregnancy Registry.
- You are breastfeeding or planning to breastfeed. There is a possibility that VIRACEPT may be excreted in breast milk. It is recommended that HIV-infected women not breastfeed their infants under any circumstances to avoid transmission of HIV. You should discuss with your doctor the best way to feed your baby.

Other warnings:

- VIRACEPT may reduce the effectiveness of birth control pills, so an alternative or additional contraceptive measure should be used.
- If you take sildenafil or other PDE-5 inhibitors and VIRACEPT together, you may be at increased risk of side effects such as low blood pressure, visual changes, and penile erection lasting more than 4 hours. If you suffer these side effects, seek immediate medical assistance.
- Do not take St. John's Wort (*Hypericum perforatum*) (see **Interactions with this medication** section)
- VIRACEPT should not be used in combination with quetiapine, due to serious and possibly life-threatening reactions, including sedation and coma. If coadministration is necessary, your doctor may need to monitor and adjust the dose of quetiapine.
- VIRACEPT should generally **not** be used with salmeterol. This may cause serious and life-threatening reactions in the heart such as:
 - Change in heart rhythm (QT prolongation)
 - Irregular or hard heartbeats, pause in heartbeats (palpitations)
 - Fast heartbeats (sinus tachycardia)

If your doctor decides you need Viracept, your doctor may change the dose or follow your condition

- VIRACEPT powder (50 mg/g) contains aspartame, a source of phenylalanine and therefore may not be suitable for persons with phenylketonuria.
- The activity of VIRACEPT in children below the age of 2 is not yet known and should not be used in this group unless the doctor decides it is needed.

As VIRACEPT has not been shown to reduce the risk of transmission of HIV to others through sexual contact, practicing safer sex, such as using condoms is very important.

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

INTERACTIONS WITH THIS MEDICATION

The following medications may interfere with the action of VIRACEPT, or VIRACEPT may interfere with the actions of these other medications. Your doctor will advise you whether these should be used or whether dosage adjustments may be necessary for VIRACEPT or these other drugs:

- Cholesterol lowering medicines - atorvastatin and fluvastatin
- carbamazepine, phenobarbital, phenytoin, dexamethasone, calcium channel blockers, quetiapine
- indinavir, ritonavir, saquinavir, rifabutin, delavirdine, omeprazole, fluticasone propionate, trazodone
- sildenafil or other PDE-5 inhibitors. Your doctor will discuss with you the possible side effects of using both VIRACEPT and PDE-5 inhibitors together (see **Other warnings**)
- bosentan, salmeterol, warfarin
- colchicine if you have liver or kidney problems

PROPER USE OF THIS MEDICATION

Usual Dose:

Take VIRACEPT exactly as prescribed by your doctor. Do not increase or decrease the number of pills or doses per day or stop taking your anti-HIV medicines before speaking with your doctor, even if you are feeling better.

The following statements apply to VIRACEPT unless otherwise prescribed by your physician. Please observe these instructions for use, otherwise you will not fully benefit from VIRACEPT.

The recommended adult dose (adults and adolescents 13 years and older) of VIRACEPT is 1250 mg given as five 250 mg

tablets or two 625 mg tablets taken two times a day or 750 mg given as three 250 mg tablets to be taken three times a day, as prescribed by your physician. VIRACEPT tablets should be taken by mouth with a meal to help achieve higher VIRACEPT levels.

The usual dose of VIRACEPT oral powder or tablets for children 2 to 13 years of age is 25-30 mg per kg three times daily as shown below. VIRACEPT oral powder and tablets should be taken by mouth, with a meal. The maximum recommended dose is 2500 mg per day. For children able to take tablets, VIRACEPT tablets may be administered instead of the oral powder.

Children Dose to be Administered Three Times Daily

Body Weight		Number of Level 1 gm Scoops ¹	Number of Level Teaspoons ²	Number of 250 mg Tablets
Kg	Lbs			
7 to < 8.5	15.5 to 18.5	4	1	---
8.5 to < 10.5	18.5 to < 23	5	1 1/4	1
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

¹ 1 level scoop contains 50 mg of VIRACEPT

² 1 level teaspoon contains 200 mg of VIRACEPT

Special considerations when taking VIRACEPT:

Tablets: VIRACEPT Tablets are film-coated to help make them easier to swallow. If you are unable to swallow the tablets, they may be placed whole or crushed in a small amount of water to disperse before swallowing. They may also be crushed and mixed with a small amount of food. Once dispersed in water or mixed with food, the entire contents must be consumed. You should rinse your glass or dish with water and consume the rinse to ensure you have consumed your entire dose. Acidic food or juice (i.e., orange juice, apple juice or apple sauce) should not be used because it may result in a bitter taste.

Oral Powder: VIRACEPT oral powder may be mixed with a small amount of water, milk, formula, soy formula, soy milk, or nutritional preparations; once mixed, the entire contents must be consumed in order to obtain the full dose. It is recommended that VIRACEPT oral powder mixed in these media be consumed immediately. If it is not consumed immediately, the mixture must be stored under refrigeration (2-8°C) for up to 6 hours. VIRACEPT oral powder should not be mixed with orange juice, apple juice, apple sauce or other liquids or foods that are acidic because the combination may result in a bitter taste. VIRACEPT Oral Powder should not be reconstituted with water in its original container.

How to optimize your use of VIRACEPT

VIRACEPT should be taken in combination with other antiretroviral agents. Clinical trials have found that combination antiviral therapy is more effective than one drug alone at reducing the amount of HIV in the blood and at reducing the development of resistance.

If you are taking both didanosine and VIRACEPT you should take VIRACEPT with a meal one hour after or more than two hours before you take didanosine.

Overdose:

In case of drug overdose, contact your health care practitioner, hospital emergency department or regional Poison Control Centre, even if there are no symptoms.

Missed Dose:

It is very important that you take your VIRACEPT and other antiretroviral therapy every dose as prescribed by your doctor. If you miss a dose you should take the next dose as soon as possible. However, if you skip a dose, do not double the next dose. You should contact your doctor or pharmacist if you are unsure what to do.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

If you notice any unwanted effects not mentioned in this leaflet or if you are unsure about the effect of this product, please consult your doctor or pharmacist.

Any drug may have unintended or undesirable effects, so-called side effects. VIRACEPT has been shown to be generally well tolerated. Side effects include diarrhea, flatulence, nausea, rash, weakness, decreased white blood cell counts and increased values for liver enzyme and kidney function tests. The side effects observed in children and adults receiving VIRACEPT are similar. Some children experienced low white blood cells (leukopenia/neutropenia), which resolved without treatment interruption in most cases.

Diarrhea is the most common side effect in people taking VIRACEPT. 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 your doctor may advise you on the appropriate treatment for diarrhea caused by the medication and may include antidiarrheal medications such as loperamide or other approved agents.

Other side effects may occur with VIRACEPT. Ask your doctor or pharmacist for more information about side effects. Your doctor and pharmacist will have a more complete list of side effects. Inform your doctor promptly about these or any other unusual symptoms. If the condition persists or worsens,

seek medical attention. Your doctor or pharmacist may be able to help you manage these side effects.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Uncommon	<p>Allergic reaction with symptoms such as swollen mouth, throat, skin, difficulty in breathing or rash.</p> <p>Low white blood cell count (leukopenia, neutropenia) with symptoms such as severe fatigue, infection or fever.</p>		√	
Rare	<p>New or worsening diabetes with high blood sugar that is sometimes severe, with symptoms such as frequent urination or increased thirst may occur.</p> <p>Specifically for hemophiliacs (type A and type B). If nosebleed, bleeding gums, unexplained bruising, or dark urine and stools.</p>		√	

New onset diabetes mellitus, high blood sugar or an increase in severity of existing diabetes mellitus has been reported in patients receiving some protease inhibitors. In some of the cases high blood sugar was severe and some of the cases also associated with ketoacidosis.

In patients with hemophilia type A and B, there have been reports of increased bleeding while taking this treatment or

another protease inhibitor. Should this happen to you, seek immediate advice from your doctor.

Changes in body fat have been seen in some patients taking antiretroviral agents. 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.

Changes in your immune system (Immune Reconstitution Syndrome) can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time, or you could develop an autoimmune disease in which your immune system reacts against your own body (e.g. Grave's disease (which affects the thyroid gland), Guillain-Barre syndrome (which affects the nervous system) or polymyositis (which affects the muscles) and it may develop at any time, sometimes months later after the start of HIV therapy). Sometimes symptoms can be severe, so if you develop high temperature (fever), joint or muscle pain, redness, rash, swelling, or fatigue or any new symptoms contact your doctor immediately.

VIRACEPT is mainly metabolized by the liver. The effects of VIRACEPT in patients with liver disease is unknown, therefore if you have liver disease it is very important that you alert your physician to any side-effects you have while taking VIRACEPT.

Make sure you tell your doctor or pharmacist of any medical problems that you may have, related or unrelated to HIV, before you start taking or while taking VIRACEPT. If, in any emergency situation, you are seeing a doctor other than your regular physician, make sure you tell them all the drugs that you are taking, including VIRACEPT.

HOW TO STORE IT

Store VIRACEPT in its original container between 15°C and 30°C.

Keep out of the reach and sight of children.
Use before the expiry date on the label.
This medicine has been prescribed for your medical problem. Do not give it to anyone else.
Discuss all your questions about your health with your doctor. If you have questions about VIRACEPT, ask your doctor, nurse or pharmacist.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 1908C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.pfizer.ca> or by contacting the sponsor, Pfizer Canada Inc. at 1-800-463-6001.

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