Viracept (nelfinavir)

Viracept is supplied as light blue, film-coated, capsule-shaped tablets imprinted with "VIRACEPT" on one side and "250 mg" on the other (top). To reduce pill burden, the drug is also available as a 625-mg tablet (bottom). Viracept is also available in an oral powder.

Also known as: Viracept mesylate, NFV, AG-1343

Background and description. Viracept is a protease inhibitor. Viracept is indicated, in combination with other antiretrovirals, for the treatment of HIV infection. The US Food and Drug Administration (FDA) approved Viracept in March 1997. The FDA gave approval to a film-coated Viracept tablet (for ease of administration) in March 2000. To reduce pill burden, 625-mg tablets are available.

Dose. The recommended dose of Viracept is 1250 mg (five 250-mg or two 625-mg tablets) twice a day or 750 mg (three 250-mg tablets) 3 times a day.

Food restrictions. Viracept must be taken with a meal or light snack. In clinical study, Viracept was administered with meals containing 517 to 759 calories, of which 153 to 313 calories were derived from fat.

Storage. Viracept tablets should be stored in a closed container and kept at a temperature of 59° to 86°F.

Patient assistance. Agouron Pharmaceuticals provides a patient assistance program. For more information, call 888.777.6637.

Side effects and toxicity. The most frequent side effect associated with Viracept therapy is diarrhea, with moderate or severe diarrhea occurring in up to 20% of those taking the drug. Metabolic (lipid and glucose) and morphologic (fat accumulation and fat atrophy) abnormalities have been associated with protease inhibitors in general.

Drug interactions. The following drugs are contraindicated with Viracept: Zocor (simvastatin), Mevacor (lovastatin), Rifadin or Rimactane (rifampin), Propulsid (cisapride), Versed (midazolam), Halcion (triazolam), DHE 45 (dihydroergotamine) and other ergot derivatives such as Wigraine and Cafergot. Viracept should be used with caution when given with Lipitor (atorvastatin); a low dose of Lipitor (10 mg) has been recommended if given concomitantly with Viracept.

When administered concomitantly, the dose of Mycobutin (rifabutin) should be reduced to 150 mg once daily and the dose of Viracept increased to 1000 mg 3 times daily. Since Viracept decreases the level of oral contraceptives when the two are co-administered, an additional or alternative method of birth control should be used. Also, St. John's Wort (*Hypericum perforatum*) is likely to decrease Viracept levels in the body and therefore should be avoided when taking Viracept. Dose reductions are required for Viagra (sildenafil), Cialis (tadalafil), and Levitra (vardenafil) in patients taking Viracept.

Viracept doses should be decreased and Kaletra increased if given together.

Additional info:

Resistance and cross-resistance. Mutations at positions 30, 77, and 80 are associated with resistance to Viracept. Viracept-resistant virus may retain sensitivity to other protease inhibitors; however, virus resistant to other protease inhibitors is likely to exhibit resistance to Viracept as well. As a result patients who experience virologic rebound on Viracept may have a better response to second-line therapy than patients who fail other protease inhibitors; however patients must switch therapies shortly after Viracept failure to achieve success with other protease inhibitors.

There are clinical data suggesting that the duration of the viral suppression afforded by Viracept is less than that afforded by other protease inhibitors, particularly in patients with baseline viral loads around 100,000 or higher (as seen with "nonresponder" patients who participated in the Agouron 511 study.

Clinical data. Agouron 511 compared a combination of Viracept/Retrovir/Epivir against a 2-drug combination of Retrovir/Epivir in antiretroviral-naïve patients. After 1 year, 52% of the patients in the Viracept arm had a viral loads less than 400 copies/mL (by an intent-to-treat analysis). The mean increase in CD4 T cell count was approxi-

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