Nelfinavir (as mesylate) is a Human Immunodeficiency Virus (HIV) protease inhibitor.

PRESENTATION:
Nelvir ® Tablet: Each film coated tablet contains Nelfinavir 250 mg as Nelfinavir Mesylate INN.

INDICATIONS:
Nelvir ® in combination with other antiretroviral agents is indicated for the treatment of HIV infection.

DOSAGE AND ADMINISTRATION:
Adults: The recommended dose is 1250 mg (five 250 mg tablets) twice daily or 750 mg (three 250 mg tablets) three times daily. Nelvir ® should be taken with a meal. Patients unable to swallow the tablets may dissolve the tablets in a small amount of water. Once dissolved, patients should mix the cloudy liquid well, and consume it immediately.
Pediatric Patients (2-13 years): In children 2 years of age and older, the recommended oral dose of Nelvir ® 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. Crushed 250 mg tablet can be used.
Dosing table for Children 2 years of age.

| Body weight | Twice daily (BID) | Three times daily (TID) |
|---|---|---|
| | 45-55 mg/kg | 25-35 mg/kg |
| | >_ 2 years | >_ 2 years |
| Kg | Lbs. | # of tablets (250 mg) | # of tablets (250 mg) |
| 10-12 | 22-26.4 | 2 | 1 |
| 13-18 | 28.6-39.6 | 3 | 2 |
| 19-20 | 41.8-44 | 4 | 2 |
| >_ 21 | >_ 46.2 | 4-51 | 32 |

CONTRAINDICATION:
Nelvir ® is contraindicated in patients with clinically significant hypersensitivity to any of its component.

PRECAUTION:
Nelfinavir is principally metabolized by the liver. Therefore, caution should be exercised when administering this drug to patients with hepatic impairment.
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.
Fat 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.

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 dosage adjustment of insulin or oral hypoglycemic agents for treatment of these events.

ADVERSE ACTION:
The majority of adverse events were of mild intensity. The most frequently reported adverse event among patients receiving Nelfinavir was diarrhea, which was generally of mild to moderate intensity.
Adverse events occurring in less than 2% of patients receiving Nelfinavir are listed below.
Body as a Whole: abdominal pain, accidental injury, allergic reaction, asthenia, back pain, fever, headache, malaise, pain, and redistribution/ accumulation of body fat.
Digestive System: anorexia, dyspepsia, epigastric pain, gastrointestinal bleeding, hepatitis, mouth ulceration, pancreatitis and vomiting.
Hemic/Lymphatic System: anemia, leukopenia and thrombocytopenia.
Metabolic/Nutritional System: increases in alkaline phosphatase, amylase, creatine phosphokinase, lactic dehydrogenase, SGOT, SGPT and gamma glutamyl transpeptidase; hyperlipemia, hyperuricemia, hyperglycemia, hypoglycemia, dehydration, and liver function tests abnormal.
Musculoskeletal System: arthralgia, arthritis, cramps, myalgia, myasthenia and myopathy.
Nervous System: anxiety, depression, dizziness, emotional lability, hyperkinesia, insomnia, migraine, paresthesia, seizures, sleep disorder, somnolence and suicide ideation.
Respiratory System: dyspnea, pharyngitis, rhinitis, and sinusitis.
Skin/Appendages: dermatitis, folliculitis, fungal dermatitis, maculopapular rash, pruritus, sweating, and urticaria.
Special Senses: acute iritis and eye disorder.
Urogenital System: kidney calculus, sexual dysfunction and urine abnormality.

DRUG INTERACTION:
Nelfinavir is an inhibitor of CYP3A (Cytochrome P450 3A). Co-administration of Nelfinavir and drugs primarily metabolized by CYP3A (e.g., dihydropyridine calcium channel blockers, HMG-CoA reductase inhibitors, immunosuppressants and sildenafil) may result in increased plasma concentrations of the other drug that could increase or prolong both its therapeutic and adverse effects. Nelfinavir is metabolized by CYP3A and CYP2C19. Coadministration of Nelfinavir and drugs that induce CYP3A or CYP2C19, such as rifampin, may decrease Nelfinavir plasma concentrations and reduce its therapeutic effect. Coadministration of Nelfinavir and drugs that inhibit CYP3A or CYP2C19 may increase Nelfinavir plasma concentrations. Drug interaction studies reveal no clinically significant drug interactions between nelfinavir and didanosine, lamivudine, stavudine, zidovudine, efavirenz, nevirapine, or ketoconazole and no dose adjustments are needed. In the case of didanosine, it is recommended that didanosine should be administered on an empty stomach; therefore, nelfinavir should be administered with food one hour after or more than 2 hours before didanosine.

Drugs that should not be co-administered with Nelfinavir

| Drug Class: Drug Name | Clinical Comment |
|---|---|
| Antiarrhythmics: amiodarone, quinidine | Contraindicated due to potential for serious and/or life threatening reactions such as cardiac arrhythmias. |
| Antimycobacterial: rifampin | May lead to loss of virologic response and possible resistance to nelfinavir or other coadministered antiretroviral agents. |
| Ergot Derivatives: dihydroergotamine, ergonovine, ergotamine, methylergonovine | Contraindicated due to potential for serious and/or life threatening reactions such as acute ergot toxicity characterized by peripheral vasospasm and ischemia of the extremities and other tissues. |
| Herbal Products: St. John's wort (hypericum perforatum) | May lead to loss of virologic response and possible resistance to nelfinavir or other co-administered antiretroviral agents. |
| HMG-CoA Reductase Inhibitors: lovastatin, simvastatin | Potential for serious reactions such as risk of myopathy including rhabdomyolysis. |
| Neuroleptic: pimozide | Contraindicated due to potential for serious and/or life threatening reactions such as cardiac arrhythmias. |
| Sedative/Hypnotics: midazolam, triazolam | Contraindicated due to potential for serious and/or life threatening reactions such as prolonged or increased sedation or respiratory depression. |

USE IN PREGNANCY AND LACTATION:
Pregnancy Category B. There were no effects on fetal development or maternal toxicity when Nelfinavir was administered to pregnant rats and rabbits. However, there are no adequate and well-controlled studies in pregnant women taking Nelfinavir. Because animal reproduction studies are not always predictive of human response, Nelfinavir should be used during pregnancy only if clearly needed.
The Centers for Disease Control and Prevention recommends that HIV-infected mothers not breast-feed their infants to avoid risking postnatal transmission of HIV. Because of both the potential for HIV transmission and the potential for serious adverse reactions in nursing infants, mothers should be instructed not to breast-feed if they are receiving Nelfinavir.

PAEDIATRIC USE:
The safety and effectiveness of Nelfinavir have not been established in patients below 2 years of age.

STORAGE CONDITON:

Store at a cool and dry place. Protect from light and moisture. Keep the medicine out of the reach of children.

HOW SUPPLIED:
Nelvir ® Tablet: Each box contains 1x10 tablets in blister pack.