NEW – NOW AVAILABLE

norvir®
(ritonavir) Tablets 100 mg

(Bottle and tablet pictured are not actual size)

Indication[1]

NORVIR® (ritonavir) is indicated in combination with other antiretroviral agents for the treatment of HIV infection.

Safety Considerations

Co-administration of NORVIR with sedative hypnotics, antiarrhythmics, or ergot alkaloid preparations may result in potentially serious and/or life-threatening adverse events due to possible effects of NORVIR on the hepatic metabolism of certain drugs. NORVIR is contraindicated in patients with known hypersensitivity to the drug or its ingredients. NORVIR is contraindicated with drugs highly dependent on CYP3A for clearance and for which elevated plasma concentrations may be associated with serious and/or life-threatening events, and with drugs that significantly reduce ritonavir. Hepatic reactions and pancreatitis, including fatalities; allergic reactions/hypersensitivity; PR interval prolongation; and elevations in total cholesterol, triglycerides, AST, ALT, GGT, CPK and uric acid have been reported with NORVIR. Patients may also develop new onset or exacerbations of diabetes mellitus, hyperglycemia, immune reconstitution syndrome, redistribution/accumulation of body fat, cross-resistance among protease inhibitors and/or increased bleeding in patients with hemophilia type A and B. Please see the Important Safety Information for more details.

NORVIR Tablets	Strength	Package Size	Unit Weight	Dimensions by Unit (LxWxH)	NDC 0074–	WAC[a] Each	List Price[b] Each
1 bottle	100 mg	30 tablets	0.13 lb	1.93" x 1.56" x 3.29"	3333-30	$257.17	$270.71

NORVIR Tablets	Strength	Case Qty	Case Cube	Case Weight	Case Dimensions
1 bottle	100 mg	24	0.17 cu ft	3.38 lb	10.19" x 7.69" x 3.75"

[a] Wholesale Acquisition Cost is the price for this drug submitted to First Data Bank and Red Book on February 15, 2010 for publication and does not include prompt pay discounts or other discounts, rebates or reductions in price. The actual price paid by wholesalers and other customers and retail price paid by consumers at a pharmacy may vary.

[b] List Price is the price for this drug submitted to First Data Bank and Red Book on February 15, 2010 for publication with respect to customers, other than wholesalers, that purchase less than one case and does not include prompt pay discounts or other discounts, rebates or reductions in price. The actual price paid by customers and retail price paid by consumers at a pharmacy may vary.

Storage Information

- Store NORVIR film-coated tablets at 20°-25°C (68°-77°F), excursions permitted to 15°-30°C (59°-86°F) [see USP controlled room temperature]
  -Dispense in original container or USP equivalent tight container (60 mL or less)
- For patient use: exposure of this product to high humidity outside the original container or USP equivalent tight container (60 mL or less) for longer than 2 weeks is not recommended

NORVIR Capsules and Oral Solution

- All forms of NORVIR remain on the market, including the soft gelatin capsules and liquid

To ORDER

- Contact your wholesaler, or call Abbott at 1-800-255-5162
- Product will ship from Abbott beginning February 19, 2010

Please see Indication and Important Safety Information, including Boxed Warning about drug interactions, on next page.

Click here to view the full Prescribing Information for NORVIR Tablets and Oral Solution.

Click here to view the full Prescribing Information for NORVIR Soft Gelatin Capsules.

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Abbott

Indication and Important Safety Information[1]

Indication

NORVIR® (ritonavir) is indicated in combination with other antiretroviral agents for the treatment of HIV infection.

Important Safety Information

WARNING:
Co-administration of NORVIR with sedative hypnotics, antiarrhythmics, or ergot alkaloid preparations may result in potentially serious and/or life-threatening adverse events due to possible effects of NORVIR on the hepatic metabolism of certain drugs.

When co-administering NORVIR with other protease inhibitors, see the full Prescribing Information for that protease inhibitor, including Contraindications and important Warnings and Precautions.

NORVIR is contraindicated in patients with known hypersensitivity to ritonavir or any of its ingredients.

NORVIR is contraindicated with drugs highly dependent on CYP3A for clearance and for which elevated plasma concentrations may be associated with serious and/or life-threatening events and with drugs that significantly reduce ritonavir. These drugs include: alfuzosin HCL, amiodarone, bepridil, flecainide, propafenone, quinidine, dihydroergotamine, ergonovine, ergotamine, methylergonovine, cisapride, St. John's wort *(hypericum perforatum)*, lovastatin, simvastatin, pimozide, sildenafil (Revatio®) only when used for the treatment of pulmonary arterial hypertension, oral midazolam and triazolam. Voriconazole is contraindicated with NORVIR as it results in a significant decrease in the plasma concentration of voriconazole.

Consider established and other potentially significant drug-drug interactions to reduce risk of serious or life-threatening adverse reactions. Alteration in dose or regimen, drug level monitoring, clinical response monitoring, or increased observations for adverse events may be recommended during co-administration of NORVIR with other CYP3A, and to a lesser extent CYP2D6, substrates. Please see full Prescribing Information for a listing of established and other potentially significant drug interactions.

Hepatic reactions, including fatalities, have occurred in patients receiving NORVIR. Monitor liver function before and during therapy, especially in patients with underlying hepatic disease, including hepatitis B and hepatitis C, or marked transaminase elevations.

Pancreatitis, including fatalities, has occurred in patients receiving NORVIR therapy, including those who developed hypertriglyceridemia. Discontinue NORVIR therapy if a diagnosis of pancreatitis is made.

Allergic reactions have been reported and include anaphylaxis, Stevens-Johnson syndrome, urticaria, mild skin eruptions, bronchospasm and angioedema. Discontinue treatment if severe reactions develop.

Ritonavir prolongs the PR interval in some patients. Cases of second and third degree atrioventricular block have been reported. Use with caution in patients with underlying structural heart disease, preexisting conduction system abnormalities, ischemic heart disease, cardiomyopathies, or when co-administering NORVIR with other drugs that may prolong the PR interval. Clinical monitoring is recommended.

Treatment with NORVIR has resulted in substantial increases in the concentration of total cholesterol and triglycerides. Monitor lipids prior to therapy and periodically thereafter.

New onset diabetes mellitus, exacerbations of diabetes mellitus, and hyperglycemia have been reported in patients receiving protease inhibitors.

Immune reconstitution syndrome has been reported in patients receiving combination ARV therapy, including NORVIR. During the initial phase of ARV treatment, patients whose immune system responds may develop an inflammatory response to indolent or residual opportunistic infections, which may necessitate further evaluation and treatment.

Redistribution/accumulation of body fat has been observed in patients receiving ARV therapy. The mechanism and long-term consequences of these events are currently unknown.

Increased bleeding has been reported in patients with hemophilia type A and B treated with protease inhibitors. Additional factor VIII may be required.

Varying degrees of cross-resistance among protease inhibitors have been observed.

NORVIR has been shown to increase triglycerides, cholesterol, SGOT (AST), SGPT (ALT), GGT, CPK, and uric acid. Appropriate laboratory testing should be performed prior to initiating NORVIR therapy and periodically thereafter.

The most common adverse reactions (>5% and of moderate to severe intensity) are abdominal pain, asthenia, headache, malaise, anorexia, diarrhea, dyspepsia, nausea, vomiting, paresthesia, circumoral paresthesia, peripheral paresthesia, dizziness, and taste perversion.

Reference: 1. Norvir [package insert]. North Chicago, IL: Abbott Laboratories.

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