
Hikma has launched Ritonavir Tablets USP

London, 20 March 2018 – Hikma Pharmaceuticals PLC (Hikma, Group) (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated Ba1 Moody's / BB+ S&P, both stable), the multinational generic pharmaceutical company, announces that its wholly owned US subsidiary West-Ward Pharmaceuticals Corp. (West-Ward), has launched Ritonavir Tablets USP, 100 mg, the first AB-rated generic to Norvir® tablets.¹

According to the FDA product approval letter, West-Ward is eligible for 180 days of generic drug exclusivity.

West-Ward's ritonavir is approved by FDA for use in combination with other antiretroviral agents for treatment of human immunodeficiency virus (HIV-1) infection.

Brian Hoffmann, President, Generics Division, said, "We are very excited to be launching Ritonavir Tablets USP. This is an exciting product which demonstrates the successful execution of our strategy to develop differentiated products. We will be launching ritonavir with additional patient support and co-pay assistance to ensure more people are able to access this life-saving medicine."

West-Ward understands that this is a very unique market that requires special consideration. It is engaging with advocacy groups to better understand how to communicate and support patients and healthcare providers. West-Ward is also launching an education and awareness campaign, including a website and direct communication.

According to IQVIA, US sales of Norvir® were approximately \$208.5 million in the 12 months ending December 2017.

Important Safety Information

BOXED WARNING: DRUG-DRUG INTERACTIONS LEADING TO POTENTIALLY SERIOUS AND/OR LIFE-THREATENING REACTIONS

Co-administration of ritonavir with several classes of drugs including sedative hypnotics, antiarrhythmics, or ergot alkaloid preparations may result in potentially serious and/or life-threatening adverse events due to possible effects of ritonavir on the hepatic metabolism of certain drugs. Review medications taken

¹ Norvir® is a registered trademark of Abbvie

by patients prior to prescribing ritonavir or when prescribing other medications to patients already taking ritonavir.

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

When co-administering ritonavir with other protease inhibitors, see the full prescribing information for that protease inhibitor, including contraindication information.

Co-administration of ritonavir 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 reactions, and with potent CYP3A inducers where significantly reduced lopinavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance and cross-resistance. These contraindicated drugs include: alfuzosin HCl, amiodarone, cisapride, colchicine, dronedarone, dihydroergotamine, ergotamine, flecainide, lovastatin, lurasidone, methylergonovine, midazolam (by mouth), pimozone, propafenone, quinidine, ranolazine, sildenafil, simvastatin, St. John's Wort (*Hypericum perforatum*), triazolam, and voriconazole.

Consider drug-drug interaction potential to reduce risk of serious or life-threatening adverse reactions. Refer to the full prescribing information for a detailed list of potential drug-drug interactions and recommendations regarding alterations in dose regimen, drug level monitoring, or increased observation for adverse events.

Hepatotoxicity, including some fatalities, has been observed in patients receiving ritonavir. 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 some fatalities, has been observed in patients receiving ritonavir; suspend therapy as clinically appropriate.

Allergic reactions/hypersensitivity have been reported in patients receiving ritonavir; discontinue treatment if severe reactions develop.

Ritonavir should be used with caution in patients with heart disease or when administering with other drugs that may prolong the PR interval.

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

Patients receiving protease inhibitor therapy may develop new onset or exacerbations of diabetes mellitus or hyperglycemia.

Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy, including ritonavir.



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

There have been reports of increased bleeding in patients with hemophilia treated with protease inhibitors.

Refer to the full prescribing information for information regarding the use of ritonavir during pregnancy.

Mothers should be instructed not to breastfeed if they are receiving ritonavir.

Various degrees of cross resistance among protease inhibitors have been observed.

In combined Phase II/IV studies, the most frequently reported adverse drug reactions among adult patients receiving ritonavir alone or in combination with other antiretroviral drugs were gastrointestinal (including diarrhea, nausea, vomiting and upper and lower abdominal pain), neurological disturbances (including paresthesia and oral paresthesia), rash, and fatigue/asthenia. In clinical trials, vomiting, diarrhea, and skin rash/allergy were the only drug-related moderate to severe adverse events observed in $\geq 2\%$ of paediatric patients

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Enquiries

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About Hikma

Hikma helps puts better health within reach every day for millions of people in more than 50 countries around the world. For 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. We're a global company with a local presence across the United States (US), the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 8,500 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner in the MENA region, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit www.hikma.com.