Triivir ®

PHARMA BUSINESS
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Triivir ®

TRIIVIR contains abacavir sulfate, which has been associated with serious and sometimes fatal hypersensitivity reactions.

* Is 3 NRTIs in 1 tablet
* Is administered 1 tablet BID, with or without food
* May be used in combination with other antiretrovirals or alone
* May help preserve future treatment options with PIs, NNRTIs, and other NRTIs

TRIIVIR is indicated in combination with other antiretrovirals or alone for the treatment of HIV-1 infection.

* TRIIVIR is one of multiple products containing abacavir. Before starting TRIIVIR, review medical history for prior exposure to any abacavir-containing product in order to avoid reintroduction in a patient with a history of hypersensitivity to abacavir
* Limited data exist on the use of TRIIVIR alone in patients with higher baseline viral load levels (>100,000 copies/mL)
* TRIIVIR is intended only for patients whose regimen would otherwise include its 3 components. Because it is a fixed-dose tablet, TRIIVIR should not be prescribed for adults or adolescents who weigh less than 40 kg or other patients requiring dosage adjustment

Composition
(abacavir sulfate, lamivudine, and zidovudine)
Each tablet contains
abacavir sulfate .....300 mg
lamivudine ..... 150 mg
zidovudine ..... 300 mg

Indication and Usage
TRIIVIR treats HIV infection in combination with other HIV medicines or alone. HIV medicines do not cure HIV infection/AIDS or prevent passing HIV to others.

* TRIIVIR is used in combination with other HIV medicines, or alone, for the treatment of HIV infection. TRIIVIR is a combination of three medicines: ZIAGEN® (abacavir sulfate), EPIVIR® (lamivudine or 3TC), and RETROVIR® (zidovudine, or ZDV). If you weigh less than 90 pounds, you should not take TRIIVIR because it may be too much medicine for your body to handle
* TRIIVIR is one of several medicines containing abacavir. Before you start taking TRIIVIR, review your medical history with your healthcare professional to make sure you have not had a severe allergic reaction to abacavir in the past
* There is limited information on the use of this triple-combination therapy in patients with viral loads >100,000 c/mL. Talk to your healthcare professional about whether TRIIVIR might be right for you

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IMPORTANT SAFETY INFORMATION
Hypersensitivity Reaction (HSR)

TRIIVIR contains abacavir sulfate, which has been associated with serious and sometimes fatal hypersensitivity reactions. Hypersensitivity to abacavir is a multi-organ clinical syndrome usually characterized by a sign or symptom in 2 or more of the following groups:

Symptom(s)
Group 1 Fever
Group 2 Rash
Group 3 Nausea, vomiting, diarrhea, or abdominal (stomach area) pain
Group 4 Generally ill feeling, extreme tiredness, or achiness
Group 5 Shortness of breath, cough, or sore throat

* Discontinue TRIIVIR as soon as a hypersensitivity reaction is suspected. Permanently discontinue TRIIVIR if hypersensitivity cannot be ruled out, even when other diagnoses are possible
* Following a hypersensitivity reaction to abacavir, NEVER restart TRIIVIR or any other abacavir-containing product because more severe symptoms can occur within hours and may include life-threatening hypotension and death
* Re-introduction of TRIIVIR or any other abacavir-containing product, even in patients who have no identified history or unrecognized symptoms of hypersensitivity to abacavir therapy, can result in serious or fatal hypersensitivity reactions. Such reactions can occur within hours

Management
* When HSR is suspected, discontinue therapy with TRIIVIR
* DO NOT RE-CHALLENGE IF HYPERSENSITIVITY CANNOT BE RULED OUT
o Abacavir should not be restarted following a hypersensitivity reaction because more severe symptoms can recur within hours and may include life-threatening hypotension and death
* To avoid a delay in diagnosis and minimize the risk of a life-threatening hypersensitivity reaction, TRIIVIR should be permanently discontinued if hypersensitivity cannot be ruled out, even when other diagnoses are possible (eg, acute onset respiratory diseases, gastroenteritis, or reactions to other medications)

Other Important Safety Information
Zidovudine has been associated with hematologic toxicity including neutropenia and severe anemia, particularly in patients with advanced HIV disease. Prolonged use of zidovudine has been associated with symptomatic myopathy.

Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues alone or in combination, including abacavir, lamivudine, zidovudine, and other antiretrovirals.

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TRIIVIR Tablets are contraindicated in patients with hepatic impairment.

Severe acute exacerbations of hepatitis B have been reported in patients who are co-infected with hepatitis B virus (HBV) and HIV and have discontinued lamivudine, which is one component of TRIIVIR. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue TRIIVIR and are co-infected with HIV and HBV. If appropriate, initiation of anti-hepatitis B therapy may be warranted.

Hepatic decompensation (some fatal) has occurred in HIV/HCV co-infected patients receiving combination antiretroviral therapy for HIV and interferon with or without ribavirin. Patients receiving interferon with or without ribavirin and TRIIVIR should be closely monitored for treatment-associated toxicities, especially hepatic decompensation, neutropenia, and anemia. Discontinuation of TRIIVIR should be considered as medically appropriate.

Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy, including TRIIVIR. During the initial phase of combination antiretroviral treatment, patients whose immune system responds may develop an inflammatory response to indolent or residual opportunistic infections (such as Mycobacterium avium infection, cytomegalovirus, Pneumocystis jirovecii pneumonia [PCP], or tuberculosis), which may necessitate further evaluation and treatment.

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. The mechanism and long-term consequences of these events are currently unknown. A causal relationship has not been established.

The most common adverse events (≥5% Grades 2-4) were nausea (19%), headache (13%), malaise and fatigue (12%), nausea and vomiting (10%), hypersensitivity reaction (8%), diarrhea (7%), fever and/or chills (6%), depressive disorders (6%), musculoskeletal pain (5%), skin rashes (5%), ear/nose/throat infections (5%), viral respiratory infections (5%), and anxiety (5%).

Presentation
TRIIVIR KIT

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