Tivicay® (dolutegravir) 50 mg tablets — A New Once daily*, Integrase Inhibitor

Now There's a Reason To Rethink First-Line Treatment in HIV

- TIVICAY® regimens have demonstrated statistically superior efficacy to Atripla®, DRV/r, and RAL In INI-naïve patients[1-3]
- No INI or NRTI resistance seen to date with TIVICAY® regimens in three large treatment-naïve studies[1-2,4]
- TIVICAY® is well tolerated with few discontinuations[1-5]
- Once daily with few DDIs or dosing restrictions*[6]
- Small tablet size; No food, fluid or time-of-day restrictions*; No boosting required[6]

For your treatment naïve patients, prescribe Tivicay® dolutegravir with your backbone of choice

* Tivicay® must be taken with other antiretroviral agents and should be administered twice daily when co-administered with certain medicines. For patients with presence of INI-class resistance (documented or clinically suspected), the recommended dose of Tivicay® is one 50-mg tablet twice daily and should preferably be taken with food to enhance exposure (particularly in patients with Q148 mutations).[6] DRV/r= darunavir/ritonavir; RAL=Raltegravir; INI=Integrase Inhibitor; NRTI=Nucleoside Reverse Transcriptase Inhibitors; DDI=Drug Drug Interaction.

1. Walmsley S *et al.* N Engl J Med. 2013; 369(19): 1807-1818. **2.** Feinberg J *et al.* ICaaC. September 10-13, 2013. Denver, Colorado. **3.** Cahn P *et al.* Lancet. 2013; 382 (9893): 700-708. **4.** Raffi F *et al.* Lancet. 2013; 381 (9868): 735-743. **5.** Raffi F *et al.* Lancet Infect Dis. 2013; 13 (11): 927-935. **6.** Tivicay® MOH approved Prescribing Information.

Indication(s): Tivicay® is indicated in combination with other anti-retroviral medicinal products for the treatment of Human Immunodeficiency Virus (HIV) infected adults and adolescents aged 12 years and older and weighing at least 40 kg.

Succinct product information:

Dosage and administration: Adults: *Patients infected with HIV-1 without documented or clinically suspected resistance to the integrase class:* The recommended dose of dolutegravir is 50 mg (one tablet) orally once daily. Tivicay® should be administered twice daily in this population when co-administered with some medicines (e.g. efavirenz, nevirapine, tipranavir/ritonavir, or rifampicin). *Patients infected with HIV-1 with resistance to the integrase class (documented or clinically suspected):* The recommended dose of dolutegravir is 50 mg (one tablet) twice daily. The decision to use dolutegravir for such patients should be informed by the integrase resistance pattern. Co-administration of Tivicay® with some medicines should be avoided in this population (e.g. efavirenz, nevirapine, tipranavir/ritonavir, or rifampicin). Adolescents aged 12 and above: In adolescents (aged from 12 to 17 years and weighing at least 40 kg) infected with HIV-1 without resistance to the integrase class, the recommended dose of dolutegravir is 50 mg once daily. Method of administration: Oral use. Tivicay® can be taken with or without food . In the presence of integrase class resistance, Tivicay® should preferably be taken with food to enhance exposure (particularly in patients with Q148 mutations). **Contraindications:** Coadministration with dofetilide. Hypersensitivity to dolutegravir or to any of the excipients. **Warnings and Precautions:** Integrase class resistance of particular concern: The decision to use dolutegravir in the presence of integrase class resistance should take into account that the activity of dolutegravir is considerably compromised for viral strains harbouring . Hypersensitivity reactions: Hypersensitivity reactions have been reported with dolutegravir, and were characterized by rash, constitutional findings, and sometimes, organ dysfunction, including severe liver reactions. Dolutegravir and other suspect agents should be discontinued immediately if signs or symptoms of hypersensitivity reactions develop. Immune Reactivation Syndrome: An inflammatory reaction to asymptomatic or residual opportunistic pathogens may arise and cause serious clinical conditions, or aggravation of symptoms. Any inflammatory symptoms should be evaluated and treatment instituted when necessary. Drug interactions: Factors that decrease dolutegravir exposure should be avoided in the presence of integrase class resistance. Metformin concentrations may be increased by dolutegravir. Patients should be monitored during therapy and a dose adjustment of metformin may be required. Osteonecrosis: Although the aetiology is considered to be multifactorial, cases of osteonecrosis have been reported in patients with advanced HIV-disease and/or long-term exposure to CART. **Undesirable effects:** Very common: Headache, nausea, diarrhoea. Common: Insomnia, abnormal dreams, dizziness, vomiting, flatulence, upper abdominal pain, abdominal pain, abdominal discomfort, rash, pruritus, fatigue, alanine aminotransferase (ALT) and/or aspartate aminotransferase (AST) elevations, creatine phosphokinase (CPK) elevations.

For full information please refer to MOH approved Prescribing Information

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WORKING ON BEHALF OF
ViiV HEALTHCARE IN HIV

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