

## **VI.2 Elements for a public summary**

### **VI.2.1 Overview of disease epidemiology**

Tenofovir disoproxil is used in combination with other drugs for the treatment of Human immunodeficiency virus, species 1 (HIV-1) and for the treatment of chronic hepatitis B, an infection with hepatitis B virus (HBV).

HIV is a blood-borne, sexually transmissible virus. According to the Joint United Nations Programme on HIV/AIDS (UNAIDS), worldwide in 2008 approximately 33.4 million people (1% of the global adult population aged 15-49 y) were infected with HIV. The prognosis in patients with untreated HIV infection is poor (Bennett NJ, 2014).

Globally, chronic HBV infection affects 350-400 million people, with disease prevalence varying among geographic regions. Chronic hepatitis B infection is considered to be a major contributor to the development of approximately 50% of cases of hepatocellular carcinoma [liver cancer] worldwide (Pyrasopoulos NT, 2014).

### **VI.2.2 Summary of treatment benefits**

Tenofovir is an antiviral medicine which is used to treat HIV or HBV infection or both. Tenofovir works by interfering with the normal working of enzymes that are essential for the viruses to reproduce themselves. In HIV Tenofovir Teva should always be used combined with other medicines to treat HIV infection. This medicine is not a cure for HIV infection. While taking Tenofovir Teva you may still develop infections or other illnesses associated with HIV infection. You can also pass on HIV or HBV to others, so it is important to take precautions to avoid infecting other people.

If administered as indicated in the Summary of Product Characteristics and taking into account the contra-indications, the warnings and precautions, tenofovir disoproxil can be considered effective in the approved indications and generally well tolerated.