

Clarification on the availability of Sanofi's Priftin® (150mg rifapentine ⁽¹⁾ coated tablets, pack of 24 tabs)

BACKGROUND

Since 1998 following the Marketing Authorization granted by the FDA for the treatment of Active Tuberculosis, Sanofi has been marketing Priftin® on the US market.

In 2014, following the publication of PREVENT-TB ⁽²⁾, a phase III clinical trial conducted by the U.S. Centers for Disease Control and Prevention, evaluating the efficacy of 3HP (Combination of Priftin® and Isoniazid weekly dosage) against nine months of daily isoniazid (9H), Priftin® labelling has been extended to treat Latent Tuberculosis in patients 2 years of age and older at high risk of progression to TB disease ⁽³⁾.

In 2019, Sanofi distributed 84,175 units of 150mg x 24 tabs of Priftin® on the US market. Priftin® is the only pharmaceutical drug containing rifapentine available in the US.

In January and February 2020, the National TB Controller Association (NTCA) reported to Sanofi, some difficulties to access to the drug in some parts of the United States.

STATEMENT

Sanofi is currently facing a challenge to supply all the demand for Priftin® as it has increased:

- Since 2018, CDC has recommended the use of Priftin in combination with Isoniazid (3HP) to treat LTBI in the US. Guidelines issued by CDC on February 14, 2020 recommend 3HP as a preferred treatment for LTBI which Sanofi expects will significantly increase demand for Priftin. Furthermore, some inventory is regularly ordered by the Canadian health authorities from US Wholesalers on a compassionate-use basis, as the product has not been registered in Canada. Sanofi does not have access to the exact quantities ordered by the Canadian health authorities. Overall, Priftin® US demand has increased in volume by 107% since 2017
- Outside of the US: after the high-level meeting of the United Nations General Assembly on the fight against Tuberculosis in September 2018, a political declaration has been signed by several endemic country's governments. In this declaration, governments commit to expand LTBI coverage in Low- and Middle-income countries. This can be facilitated by the introduction of the shorter 3HP regimen. Priftin® is the only WHO prequalified 3HP for short-course treatment of LTBI. Uptake of Priftin® in those countries that collectively account for more than 90% of the global need for latent TB infection preventive therapy, has been much faster than expected.

Sanofi has substantially increased the production volume of Priftin and is working to increase its manufacturing capacity but expects that the sharp ramp up after years of stable, low demand will create tension in the delivery schedule. Sanofi will do its best effort to meet demand in 2020 and is closely monitoring the distribution channel inventory to help ensure Priftin availability to customers.

The anticipated arrival of Generic competitors on donor-funded markets outside of the US will be expected to increase availability of rifapentine in the coming months that may bring some relief for the overall supply situation.

- (1) *The trial enrolled over 8000 participants and found that AN ACTIVIST’S GUIDE TO Rifapentine FOR THE TREATMENT OF TB INFECTION*
KEY TERMS TB INFECTION, sometimes referred to as latent TB infection (LTBI), is caused by infection with *Mycobacterium tuberculosis*. RIFAMYCINS are a class of antibiotics that includes the drugs rifampicin, rifapentine, and rifabutin. They share a similar chemical structure and method of action. **K N O W Y O U R T P T REGIMENS:** When abbreviating TB drug regimens, H = isoniazid; P = rifapentine; and R= rifampicin (sometimes called rifampin). •3HP = 12 weeks of isoniazid and rifapentine taken together once a week •1HP = one month of isoniazid and rifapentine taken together once a day •3HR = three months of isoniazid and rifampicin taken together once a day •4R = four months of daily rifampicin •IPT = isoniazid taken daily for six, nine, 12, or up to 36 months April 2019
 By: Mike Frick | Reviewed by: the Community Research Advisors Group, Elizabeth Bonomo, Erica Lessem, John Mdluli, Lindsay McKenna, Regina Osih, and members of the Family Clinical Research Unit (FAM-CRU) community advisory board 2 3HP was noninferior to (no worse than) 9H in preventing TB disease.1 Participants taking 3HP were more likely to complete treatment than those on 9H. PREVENT-TB also assessed the effectiveness of 3HP in nearly 400 people living with HIV (PLHIV) and over 900 adolescents and children as young as two years old. Among PLHIV, 3HP was noninferior to 9H in preventing TB disease, and people taking 3HP were more likely to complete treatment.2 Based on when the study started, participants with HIV in the trial were not on antiretroviral therapy (ART). Today, TPT should always be offered together with ART (read “What about people living with HIV?” below.) Children taking 3HP in the PREVENT-TB study also did well and were more likely to complete treatment than those receiving 9H.3 The BRIEF-TB trial, conducted by the AIDS Clinical Trials Group at the U.S. National Institutes of Health, evaluated the efficacy of 1HP compared with 9H. This phase III trial enrolled 3000 adults living with HIV and assessed safety, treatment completion, and efficacy over three years of follow-up.4 The trial found that 1HP was noninferior to 9H in preventing TB and death from either TB or unknown cause. Participants taking 1HP were significantly more likely to complete treatment than those on 9H. Further studies to assess whether 1HP is effective in other populations, including HIV-negative people, children, and pregnant women, are planned.
- (2) *The active substance of Priftin® is rifapentine, which belongs to a class of drugs called rifamycins and is the backbone of newer short-course TPT : when combined with a second TB drug, isoniazid, rifapentine forms the 3HP regimen (taken once weekly for 12 weeks) and the 1HP regimen (taken once a day for one month). The 3HP and 1HP regimens offer shorter alternatives to the older standard of care, called isoniazid preventive therapy (IPT), in which people take isoniazid every day for between six and 36 months.*
- (3) *also referred to as TB preventive therapy - TPT is one of the most powerful ways to prevent TB). If left untreated, TB infection can develop into active TB disease, the form of TB that makes people sick and is capable of being transmitted from one person to another. Yet only a very small proportion of the people who may benefit from TPT receive it. TPT has two major goals: 1) protect people who are already infected with the TB bacterium from falling ill with active TB disease, and 2) shield people who are uninfected but at risk of TB exposure from getting infected in the first place. Preventive therapy is one of the best ways to keep individuals and families safe from TB, which in turn helps communities become—and remain—TB free.*