

## Taiwan CDC 12-Dose Regimen for Latent Tuberculosis Treatment Consent

Medicine: Rifapentine 150mg/Tab ( Priftin<sup>®</sup> 150mg ) + Isoniazid 300 mg/Tab

Name:

Chart No.:

I. Indications: Latent Tuberculosis (TB) Infection  
(Being infected is not contagious. To effectively reduce the risk of developing active TB disease, please take the full course of latent TB treatment.)

II. Administration:  
You will take Rifapentine and Isoniazid once weekly with a total of 12 doses. The duration will take 3 months (12 weeks).

III. Adverse Reactions:  
Mild symptoms, such as nausea or vomiting, muscle aches, weakness, fatigue may occur in 21% of those who take 12-dose regimen. Most of these symptoms will not interfere with your daily activities, and only 2% of people who experienced adverse reactions may discontinue treatment. Additionally, severe hypersensitivity reactions may occur (less than 1%). If you have any symptoms, such as hypotension, angioedema, syncope, etc., please stop taking medicine and return for medical evaluation immediately.

IV. Precautions:

- i. Medications of 12-dose regimen must be prescribed by physicians.
- ii. You must take 12-dose regimen under Directly Observed Treatment Short course (DOTS) program. The observers will deliver drugs to you at appointed place and time, and also to monitor possible adverse reactions.
- iii. Please contact the public health center once you get your medications, the public health nurse will help you to plan your medication schedule.

- **The medications of 12-dose regimen are provided by Taiwan CDC, and those with latent TB infection using this regimen must participate DOTS program.**
- The 12-dose regimen is one of the standard latent TB infection treatment regimens recommended by World Health Organization. Because the drug license application of rifapentine is now under review by Taiwan Food and Drug Administration (TFDA), using 12-dose regimen is not applicable for drug injury compensation. The indications of isoniazid, which has been approved by TFDA, do not list using for latent TB infection treatment, but U.S. FDA has approved isoniazid in combination with rifapentine for a new indication of latent TB treatment since 2014.
- **I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it, and any questions that I have asked have been answered and explained to me. I consent to use the 12-dose regimen.**

Signature of Physician :

Date : \_\_\_\_\_

Signature of Patient/Guardian:

Date : \_\_\_\_\_