



June 30, 2021

## Provincial TB Services Update: Rifapentine (Priftin®) in Canada

In August 2020, the use of rifapentine (Priftin®) in Canada was suspended due to concerns regarding product detection of nitrosamine impurities in the formulated tablets. The nitrosamine impurities are unwanted molecules formed in the process of making rifapentine. Health Canada is continuing to work with the rifapentine manufacturer to ensure this issue is resolved as quickly as possible.

Some nitrosamines are probable carcinogens in humans. Exposures to low levels of nitrosamines occur through tobacco products, air pollution and in foods such as processed meats, and dairy products. Nitrosamines are also naturally found in water and vegetables. These impurities are not expected to cause harm when ingested at very low levels.

### Benefit-Risk Assessment

The Public Health Agency of Canada (PHAC) conducted a Benefit-Risk Assessment with input from Health Canada, Indigenous Services Canada (ISC) and leading TB experts. This assessment was on the use of rifapentine in the three-month regimen of isoniazid and rifapentine, for latent TB infection (LTBI). The outcomes of the assessment were shared with the Chief Medical Officers of Health across Canada.

As of March 2021, Canada's *List of Access to Drugs in Exceptional Circumstances* includes rifapentine (Priftin®) to address urgent public health needs not managed by other therapies. The rifapentine regimen remains an acceptable alternative treatment for LTBI and has been shown to be as effective as the standard LTBI treatment while demonstrating higher treatment completion rates.

**The benefits of the three-month once-weekly regimen of rifapentine and isoniazid (3HP) are felt to outweigh the potential health risks posed by the nitrosamine impurity detected.**

**This regimen is recommended when there is a high risk of non-adherence or non-completion of treatment, or where other treatment alternatives are not feasible or suitable.**

### Provincial TB Services

- A patient-centered approach to LTBI treatment is an essential component of TB care and an important step towards TB elimination.
- The goal is to offer clients a LTBI regimen that is more likely to be started. In BC, there are three LTBI treatment regimens available:
  - 4 months of daily rifampin
  - 3 months of weekly rifapentine and isoniazid
  - 9 months of daily isoniazid
- The rifapentine regimen will be offered to clients with LTBI where appropriate; of note, this regimen is completed by directly observed therapy (DOT). The [BCCDC rifapentine & nitrosamine handout](#) is available to support informed consent.

## Health Authority TB Programs

- If your TB program identifies clients where the rifapentine regimen will support completion of treatment or other alternatives are not suitable, it can be offered.
- The [BCCDC rifapentine nitrosamine handout](#) is available to support informed consent.

## Rifapentine Supply

- As of July 2021, there are limited rifapentine supplies on hand at the BCCDC Pharmacy.
- The BCCDC Pharmacy is working directly with the drug manufacturer to procure additional supply.
- In the unlikely event that the rifapentine supply at the BCCDC is exhausted, ISC has procured a supply for Indigenous clients living in or out of community (on or off reserve).

## BCCDC Website

Find additional resources in the TB section of our website:

- The TB Care & medications section (*I have latent TB Infection*) includes the rifapentine regimen with LTBI timeline of care, the BCCDC pharmacy medication sheets and the rifapentine & nitrosamine handout  
[www.bccdc.ca/health-info/diseases-conditions/tuberculosis#Care--&--Medications](http://www.bccdc.ca/health-info/diseases-conditions/tuberculosis#Care--&--Medications)
- The TB Clinical Resources section (*Medication forms*) include this communication and the rifapentine & nitrosamine handout  
[www.bccdc.ca/health-professionals/clinical-resources/tuberculosis-guidelines](http://www.bccdc.ca/health-professionals/clinical-resources/tuberculosis-guidelines)

If you have any further questions, please do not hesitate to connect with us.

Regards,



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## References

[www.canada.ca/en/health-canada/services/drugs-health-products/access-drugs-exceptional-circumstances/list-drugs-urgent-public-health-need.html](http://www.canada.ca/en/health-canada/services/drugs-health-products/access-drugs-exceptional-circumstances/list-drugs-urgent-public-health-need.html)

[www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/nitrosamine-impurities.html](http://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/nitrosamine-impurities.html)