



RIFAPENTINE & NITROSAMINE

Rifapentine (Priftin®) is an antibiotic given with other medicines to treat latent (sleeping or dormant) tuberculosis (TB) infection. Treating latent TB infection (LTBI) with antibiotics is the best way to prevent active TB disease.

What you need to know

- Rifapentine (RIF-a-PEN-teen) is given with another medicine called isoniazid once a week for 12 weeks to treat LTBI
- This is a shorter treatment compared to other LTBI treatments which can last between 4 - 9 months
- Rifapentine may be the right option for you if you can't take other LTBI medicines or if taking treatments for longer than 3 months doesn't work for you
- If you choose **NOT** to take rifapentine, there are other options to treat LTBI
- Talk to your health care provider about LTBI treatment options. They will help you make the best decision for your health

Rifapentine and nitrosamine impurity

Sometimes, unwanted molecules (particles) are formed when drugs are made. These unwanted molecules are called impurities. Low levels of a nitrosamine (NI-tro-SA-mean) impurity have been found in rifapentine.

What is the health risk of a nitrosamine impurity?

Some nitrosamines are probable carcinogens in humans. This means that long-term exposure to a level above what is considered safe could increase the risk of cancer.

Everyone is exposed to nitrosamines

They are common in some foods such as processed meats, dairy products and vegetables.

Nitrosamines may also be found in water, air pollution and tobacco products. These impurities are not expected to cause harm when ingested at very low levels.

What is the health risk of taking rifapentine right now?

Rifapentine has higher levels of a nitrosamine impurity than what is normally considered acceptable. Health Canada is working with the manufacturer to ensure this issue is resolved as quickly as possible. This specific nitrosamine impurity has not been shown to develop cancer in animals or humans.

Does taking rifapentine right now increase cancer risk?

The nitrosamine impurity in rifapentine has been shown to cause gene changes (mutations) in the lab setting. The structure of the impurity looks similar to other nitrosamines that have been shown to develop cancer in humans.

Without being exposed, everyone already has nearly a 1 in 2 chance of developing cancer in their lifetime.

Some risk related to impurities in drugs is considered acceptable. The risk is considered acceptable as long as there is no more than one additional cancer case for every 100,000 people exposed to a drug impurity over a lifetime.

Drawing from animal data and data from a different nitrosamine issue, Health Canada has estimated that up to 1 person out of 34,000 patients exposed to this nitrosamine may develop cancer.

TB experts and Health Canada carefully looked at the absence of evidence of human cancer and recommended rifapentine remain as a treatment option in Canada.

What do TB experts recommend?

Canadian TB experts have weighed the potential risks related to the nitrosamine impurity in rifapentine against the known benefits of using rifapentine to treat LTBI.

For most people, the benefits of taking rifapentine with the nitrosamine impurity are greater than the risk of leaving their LTBI untreated.

Treating LTBI is the best way to prevent active TB disease.

Who to call with questions

- Your TB Care Provider:

- Vancouver TB Services Clinic
604-707-2692
- New Westminster TB Services Clinic
604-707-2698
- BCCDC Vaccine and Pharmacy Services 604-707-2580