

Nitrosamines and Rifamycin: Patient Education

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About Us

New Mexico Department of
Health TB Program.

The New Mexico Tuberculosis Program (TBP) is a centralized program that is responsible for TB management and treatment activities throughout New Mexico (NM).

- There are 33 counties and 56 health offices in NM.
- Use LTBI short course regimens (3HP and 4R) unless contraindicated



What actions did your agency implement after the notification of nitrosamine impurities in rifamycin products?

- Put all rifamycin's on hold
- Continue to utilize all rifamycin's
- Only treated patient's with active TB
- Unsure

Polling Question

Patient Education/Consent Form

Nitrosamine Impurities in TB Medications

On August 26, 2020, the FDA became aware of nitrosamine impurities in certain samples of rifampin and rifapentine.

What are nitrosamines?

Nitrosamines are common in water and foods, including cured and grilled meats, dairy products and vegetables. Everyone is exposed to some level of nitrosamines.

- The nitrosamine found in rifapentine is 1-cyclopentyl-4-nitrosopiperazine (CPNP)
- The nitrosamine found in rifampin is 1-methyl-4-nitrosopiperazine (MNP)

What are the risks of nitrosamine impurities?

Nitrosamine impurities may increase the risk of cancer if people are exposed to them above acceptable levels and over long periods of time, but a person taking a drug that contains nitrosamines at-or-below the acceptable daily intake limits every day for 70 years is not expected to have an increased risk of cancer.

What is the FDA doing?

- The FDA is working with manufacturers to identify and address the origin of the impurities.
- The FDA recognizes that the benefits of rifampin and rifapentine outweigh any potential risk. The FDA has temporarily adjusted the acceptable limits of nitrosamine in the medications until a resolution is found.

What is an acceptable intake of Nitrosamine?

Just How Much is 1 Part Per Million (PPM)?

In one olympic sized swimming pool there are 660,000 gallons.



1 PPM = 1 1/4 two-liter bottles



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Medication	Normal Intake Limit	Temporary Intake Limit
Rifampin	0.16 ppm of MNP	5 ppm of MNP
Rifapentine	0.1 ppm of CPNP	14 ppm of CPNP

What should I do if my prescription medication has a nitrosamine impurity?

Tuberculosis is a potentially deadly disease that affects the lungs and sometimes other parts of the body, and the risk of not taking the medicine outweighs any potential risk from nitrosamine impurities. Patients should discuss with their health care professional about their concerns and treatment options.

Acknowledgment

Please sign and date below after selecting whether you accept or decline treatment with rifampin or rifapentine. Your signature indicates that the information above has been reviewed with you by Department of Health staff, you have received a copy of this information sheet, and your selection to accept or decline therapy with Rifampin or Rifapentine.

Accept

Decline

Signature _____

Date _____

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PUBLIC HEALTH DIVISION

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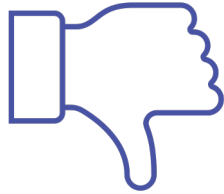


Did your organization develop materials to inform and/or obtain consent prior to offering patients treatment using rifamycin?

- No
- Yes
- Unsure
- In process

Polling Question

Where are we now



Few declinations



Helpful information



Hard to explain the information to some patients



Decisions

```
graph LR; A[Decisions] --- B[Continue use of current form]; A --- C[Revise form]; A --- D[Eliminate form];
```

Continue use of current form

Revise form

Eliminate form



Many Thanks

- ❖ TB Medical Director
- ❖ NM DOH Pharmacist
- ❖ TB Nurse Consultants
- ❖ Local TB nurses

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